EPA Registration # 67702-31

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Walter G. Talarek
Authorized Agency
W. Neudroff GmbH KG
1008 Riva Ridge Drive
Great Falls, VA 22066

APR 15 2014

RE: Confidential Statement of Formula (CSF) Amendment for Ferroxx MP (EPA Reg. No. 67702-31); Your Letter to L. Hollis Dated April 4, 2014

Dear Mr. Talarek:

The Biopesticide and Pollution Prevention Division (BPPD) has received and reviewed the letter referenced to above, and met with you in person on April 7, 2014, to discuss the action request to add three Alternate Formulations to Ferrox MP (EPA Reg. No. 67702-31). The Agency remains of the position, under 40 CFR 152.42(c), that your action, submitted as a Fast Track Amendment in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is not acceptable.

Specifically, your three proposed Alternate Formulations differ significantly in inert ingredient composition from your Basic Formulation CSF dated April 17, 2013 ("Basic"), so as to warrant supportive data indicating no significant difference in product chemistry or human health toxicity between these formulations and your Basic Formulation. At a minimum, the Agency recommends that you resubmit this request to include product chemistry data, a Manufacture Safety Data Sheet (MSDS) for each new inert ingredient, and an updated manufacturing process for your product. Such a request should be submitted as an amendment under the Pesticide Registration Improvement Act (PRIA 3). For this action, the Agency believes that the PRIA 3 category of B681, "Amendment; unregistered source of active ingredient, requires data submission," would apply.

Should you have any questions, you may contact Gina Burnett directly at (703) 605-0513 or via email at burnett.gina@epa.gov.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES

SYMBOL ►	7511P							
SURNAME ►	Burnett							
DATE ►	4/14/2014							

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

ROUTING AND TRANSMITTAL SLIP Date: 4/14/2014

TO: *(Name, office symbol, room number, building, Agency)*		
Sheryl Reilly, Associate Chief, BPB/BPPD/OPP	SR	4/14/14
Linda Hollis, Chief, BPB/BPPD/OPP	LH	4/15
Gina Burnett, Regulatory Action Leader, BPB/BPPD/OPP		

	Action		File		Note and Return
X	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify		

REMARKS

Response to Walt Talarek re Unacceptable CSF Amendment

Walt submitted an amendment to add three Alternate Formulations (CSFs enclosed). We replied in a memo dated March 20, 2014 (enclosed). He sent a response memo April 4, 2014 (enclosed). We met in person on April 7, 2014.

Our response to that meeting is enclosed for your review/signature.

Thanks!
Gina

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions.

FROM: *(Name, org. symbol, Agency/Post)*	Room No.– Bldg.
	S-8946
Gina Burnett, OPP/BPPD/BPB	Phone No. 703-605-0513

Pages 4-6 Claimed confidential by submitter

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Walter G. Talarek
Authorized Agent
W. Neudorff GmbH KG
1008 Riva Ridge Drive
Great Falls, VA 22066

MAR 20 2014

Subject: Fast Track Amendment to Three Alternate Formulations
Product Name: Ferroxx MP
EPA Reg. No: 67702-31
Your Submission Dated November 20, 2013

Dear Mr. Talarek:

The Biopesticide and Pollution Prevention Division (BPPD) has received and reviewed the application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and has concluded that your application is **not acceptable**. Specifically, the three Alternate Formulations proposed differ significantly in inert ingredient composition from your Basic Formulation CSF dated April 17, 2013 ("Basic"). This request must be supported with data indicating that there is no significant difference in product chemistry, human health toxicity or nontarget organism toxicity between these formulations and your Basic. Significant differences in any area will likely be considered a new product and require registration under FIFRA. Please resubmit this request as either an amendment under the Pesticide Registration Improvement Act (PRIA 3) or a new product registration under PRIA 3, at your discretion.

Should you have any questions, you may contact Gina Burnett directly at (703) 605-0513 or via email at burnett.gina@epa.gov.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES

SYMBOL ►	7511P	7511P						
SURNAME ►	Burnett							
DATE ►	3/18/2014	3/19/14						

EPA Form 1320-1A (7/90)

OFFICIAL FILE COPY

ROUTING AND TRANSMITTAL SLIP Date: 3/18/2013

TO: *(Name, office symbol, room number, building, Agency)*		
Sheryl Reilly, Associate Chief, BPB/BPPD/OPP	SR	3/19/14
Linda Hollis, Chief, BPB/BPPD/OPP	LH	3/20
Gina Burnett, RAL/Biologist, BPB/BPPD/OPP		

	Action		File		Note and Return
X	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify		

REMARKS

Unacceptable CSF Amendment for EPA Reg No. 67702-31

The appplicant is requesting to add three Alternate Formulations. Each Alternate contains new ingredients in substantial concentrations. I spoke with Angela Gonzales on 3/18/2014. She agrees that none of these CSFs are acceptable Alternate Formulations due to the significance of the requested changes. Specifically, toxicity profiles are expected to be different between these formulations and the Basic Formulation. These formulations should be handled as one or more new product registrations.

Please comment or concur.

Thanks,
Gina

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions.

FROM: *(Name, org. symbol, Agency/Post)*	Room No.– Bldg.
	S-8946
Gina Burnett, OPP/BPPD/BPB	Phone No. 703-605-0513

Amendment Not Acceptable

BPPD Formulation Amendment Check List

Fast Track ☒ and PRIA Actions B680 ☐, B681 ☐,B730☐

EPA Reg. No.: 67702-31 **RAL:** G. Burnett **Application Date:** 11/20/2013

#	Check list Item	
1.	**Application Form** (EPA Form 8570-1) - signed & complete including package type? **IF NO, STOP!** Call applicant and have them correct application and resubmit.	✓
2.	**Final printed labeling** received for previous action? **IF NO, STOP!** E-mail applicant and request final printed labeling.	✓
3.	Does the registration notice have terms/conditions (ex: storage stability data)? If so have the terms/conditions been met?	N/A
4.	**Confidential Statement of Formula** (CSF) EPA Form 8570-4 Basic Formula ☐ Alternate Formula(s) ☒ 1, 2 & 3	
a.	CSF Review completed? **IF YES, SKIP to next item.**	✓
b.	CSF is signed and dated? **IF NO, CALL APPLICANT.**	✓
c.	Completely filled out: CAS numbers, pH, flashpoint, flammability, if applicable?	✓
d.	Are the totals accurate?	✓
e.	Certified limits agree with 40 CFR 158.175? Note that if preliminary or 5 batch analysis differ from Section 158.175(b), limits based on batch analysis would need to be proposed under Section 158.175(c).	✓
f.	Viability (if live microbial, i.e., cfu/gram)? NA ☒	N/A
g.	PC codes assigned on CSF for actives & inerts plus 40 CFR 180.910, 180.920, and 180.930 codes noted for products that have food or feed uses?	no
h.	List 1 inert ingredient(s) present in the formulation?	no
i.	Alternate formula(s) do not require different labeling from basic CSF or other alternate CSFs. NA ☐	these require data/new registr
j.	Source for a.i. is a registered pesticide? (When a proposed alternate or new basic formula involves a new registered manufacturing-use product as the active ingredient source it must be determined whether the manufacturing-use products used to formulate are similar enough to warrant use of existing product specific data such as acute toxicity.)	no
k.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? **If YES**, RAL must evaluate label directions for compliance with 40 CFR 180.1071.	N/A
5.	**Data and Data Matrix** present. (EPA Form 8570-35)	no
a.	a) Using Selective Method? [[**IF NO, SKIP to item 5 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.**]]	data needed
b.	Complete Data Matrix. Minimum Data Matrix for registration includes: product specific acute toxicity, product chemistry, and efficacy data for public health pests claimed on label.	
c.	Adequate product specific data submitted?	

d.	Registered source used for active ingredient? **IF YES, SKIP to ITEM 5.** (Active ingredient is from a registered source and generic data should be satisfied by registered source. **IF NO**, generic data needed.	no
e.	Data passed PR Notice 86-5 for formatting and MRID number assignment?	N/A
f.	Public copy of Data Matrix provided? (PRN 98-5)	N/A
6.	**Certification with Respect to Citation of Data** (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [Note: If no data are required or submitted, a Certification with Respect to Citation of Data form is not needed. This is often true for minor amendments.]	
a.	Did applicant check a Method of Support?	
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?	
c.	Is the form signed and dated?	
d.	Check form and Data Matrix; are Exclusive Use data cited from other sources?	
	IF YES, is the required authorization letter included in application? NA ☐	
7.	**Formulators Exemption** (EPA Form 5870-27)	
a.	If registrant is using a registered source active ingredient in the formulation, is form filled out completely and signed? NA ☐	
8.	**Science Review** completed? Comments: These are significant formulation changes that would likely change the tox Profile of this product. No data or MSDS was submitted. These should be evaluated under a new registration G. Burnett 3/18/2014	

* Claimed confidential by submitter*

Please read instructions on reverse before co ng form. Form Approved. OMB No. 2070-0060 Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702-31	Linda Hollis	[x] None [ ] Restricted
4. Company/Product (Name) Ferroxx MP	**PM#** 91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. 67702-31

Product Name Ferroxx MP

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to product's registration which adds three (3) alternate formulations. See the enclosed letter to Ms. Linda Hollis, PM 91, for a full explanation of the amendment.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information [ ] Label [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions [ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title
[signature]	Authorized Agent
4. Typed Name Walter G. Talarek	**5. Date** November 20, 2013

6. Date Application Received (Stamped)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 2, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

WALTER G TALAREK
W. NEUDORFF GMBH KG
POSTFACH 1209
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

PRODUCT NAME: FERROXX MP
COMPANY NAME: W. NEUDORFF GMBH KG
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 67702-31
EPA RECEIPT DATE: 11/21/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-6928.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

FIFRA

CONFIDENTIAL BUSINESS INFORMATION
DOES NOT CONTAIN
NATIONAL SECURITY INFORMATION (EO 12356)

SOME INFORMATION IN THE ATTACHED MATERIAL MAY BE ENTITLED TO TREATMENT AS TRADE SECRET OR PROPRIET DATA UNDER SECTION 7(d) AND SECTION 10 THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE AS (FIFRA) AS AMENED.

ANY PERSON HANDLING OR USING THE ATTACHED DATA IN ANY WAY IS RESPONSIBLE FOR PREVENTING UNAUTHORIZED DISCLOSURE WHILE IN HIS/HER PROCESSION. SECTION 12(a)(2)(D) MAKES IT UNLAWFUL FOR ANY CONFIDENTIAL INFORMATION (EXCEPT TO PERSONNEL NEEDING THE INFORMATION FOR THE PERFORMANCE OF OFFICAL DUTIES). A PENALTY OF UP TO $10,000 FINE AND UP TO 3 YEARS IMPRISONMENT MAY RESULT FROM CONVICTION OF A VIOLATION OF SECTION 12(A)(2)(D).

SECTION 10(f) MAKES IT A CRIME FOR EMPLOYEE TO DISCLOSE CONFIDENTIAL INFORMATION EXCEPT AS AUTHORIZED BY SECTION 7 AND 10 OF FIFRA. A PENALTY OF UP TO $10,000 FINE AND UP TO ONE YEAR IN JAIL MAY RESULT FROM CONVICTION OF A VIOLATION OF SECTION 10(f).

THE ATTACHED INFORMATION IS NOT TO BE PUBLISHED, REPRODUCED, PUBLICLY DISCUSSED, OR INCLUDED IN RESPONSE TO A FREEDOM OF INFORMATION AUTHORIZATION OF THE APPROPIATE DIVISION DIRECTOR OR HIS/HER DESIGNEE.

Pages 15-32 Confidential Statement of Formula may be entitled to confidential treatment

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG 05 2013

W. Neudorff GmbH KG
c/o Walter G. Talarek, P.C.
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

Subject: Confidential Statement of Formula (CSF) Amendment to consolidate the basic and alternate formulation CSFs into one basic formulation CSF, add two new producers, and add new suppliers of one inert ingredient.
Ferroxx MP
EPA Reg. No.: 67702-31
Your submission dated April 17, 2013
Decision Number: 478266

Dear Mr. Talarek:

The amendment to the basic formulation CSF referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5), as amended, has been received and reviewed, and the amendment is acceptable. The basic formulation CSF dated April 17, 2013 have been added to your file and is considered current and updated. The previous basic formulation CSF and all alternate formulation CSFs on file with the Agency are considered outdated and obsolete. Should you have any questions, you may contact Mr. Colin Walsh directly at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES								
SYMBOL ▶								
SURNAME ▶								
DATE ▶								

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COP

* U.S. Government Printing Office: 2005 906-800 (ms

RISK ASSIGNMENT FORM

Biopesticide & Pollution Prevention Division/Biochemical Pesticides Branch

A	Completed by Team Leader

REGULATORY ACTION LEADER/NOWCC: Colin Walsh	BPB X MPB_____
Description of Action: Amendment	EPA File Symbol/Reg No. 67702-31

Decision No. 478266	Submission No. 933871	Fee for Service Action Code:

FQPA Action Code:	Non-FQPA Action Code:	PRIA FEE AMOUNT: $

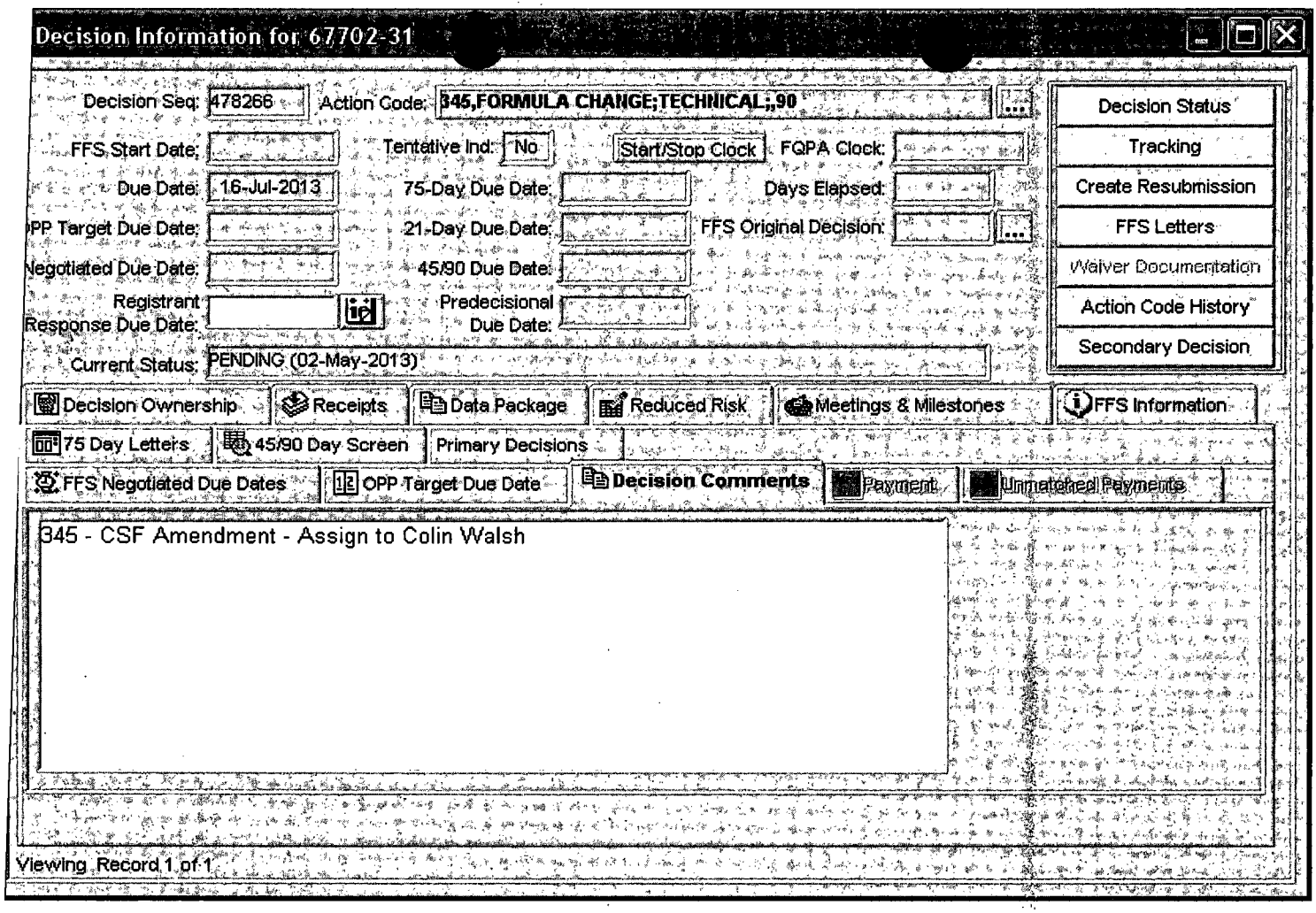
	MONTH	DAY	YEAR
APPLICATION DATE	4	17	2013
EPA PIN DATE	4	17	2013
DATE RECEIVED FROM FRONT END	4	23	2013
Date sent to Reviewer	4	23	2013
DATE SENT TO SCIENCE	4	29	2013
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			DATE DUE OUT OF AGENCY

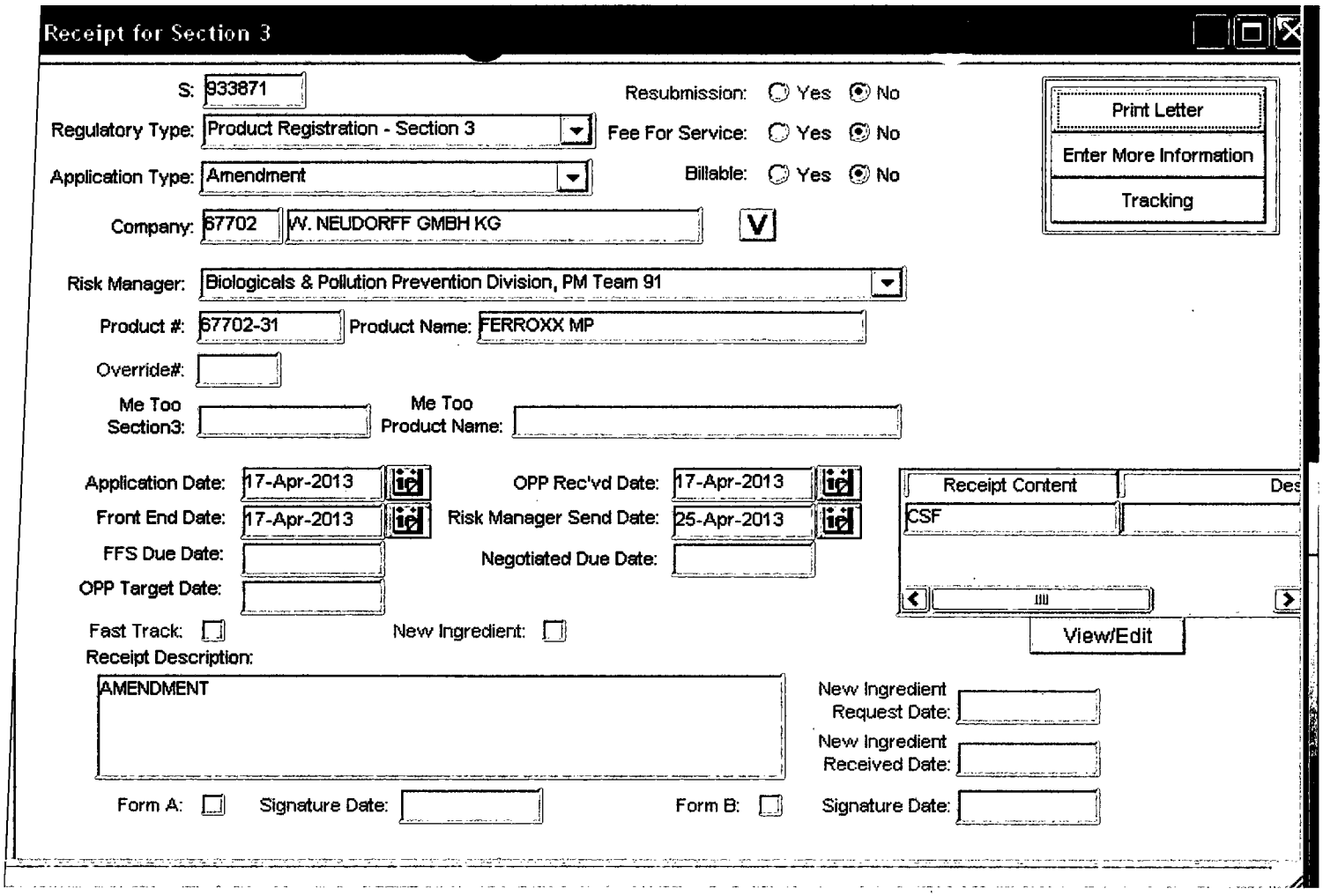
Type of Data:	Product Chemistry	Acute Toxicology	Efficacy	Environmental Fate	Ecological Effects	Chronic Toxicology	Exposure/ Residue

COMMENTS: 345 CSF Amendment - Assigned to Colin Walsh

ATTACHMENTS: ☑-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID:	RESPONSE CODE:_____ RESPONSE DATE:_____


Decision Information for 67702-31
Decision Seq: 478266
Action Code: 345,FORMULA CHANGE;TECHNICAL;;90
FFS Start Date:
Tentative Ind: No
Start/Stop Clock
FQPA Clock:
Due Date: 16-Jul-2013
75-Day Due Date:
Days Elapsed:
PP Target Due Date:
21-Day Due Date:
FFS Original Decision:
Negotiated Due Date:
45/90 Due Date:
Registrant Response Due Date:
Predecisional Due Date:
Current Status: PENDING (02-May-2013)
Decision Status
Tracking
Create Resubmission
FFS Letters
Waiver Documentation
Action Code History
Secondary Decision
Decision Ownership
Receipts
Data Package
Reduced Risk
Meetings & Milestones
FFS Information
75 Day Letters
45/90 Day Screen
Primary Decisions
FFS Negotiated Due Dates
OPP Target Due Date
Decision Comments
Payment
Unmatched Payments
345 - CSF Amendment - Assign to Colin Walsh
Viewing Record 1 of 1



345 CSF Amendment

↓

C. Walsh

4/29/2013 GB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 25, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WALTER G TALAREK
W. NEUDORFF GMBH KG
POSTFACH 1209
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

PRODUCT NAME: FERROXX MP
COMPANY NAME: W. NEUDORFF GMBH KG
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 67702-31
EPA RECEIPT DATE: 04/17/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 605-0513.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {9338715~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 91

Receipt No. S-	933871
EPA File Symbol/Reg. No.	67702-31
Pin-Punch Date:	4/17/2013

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted: 345

Amount Due: $ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: TEAM TWO Date: _____

Remarks:

345 CSF Amendment / Non-PRIA
G. Burnett, BPPD
4/23/2013

* Claimed confidential by submitter*

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702-31	Linda Hollis	[ ] None [ ] Restricted
4. Company/Product (Name) Ferroxx MP	**PM#** 91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 20066-1620

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amendment to product's registration which adds new producers of the product and new sources of an inert ingredient. See the enclosed letter to Ms. Linda Hollis, PM 91, for a full expanation of the amendment. A revised Confidential Statement of Formula is enclosed.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-758-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
W G Talarek	Authorized Agent	
4. Typed Name Walter G. Talarek	**5. Date** April 17, 2013	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Decision #: 425379
DP #: (373965)
PRIA
Parent DP #:
Submission #: 866101

DATA PACKAGE BEAN SHEET

Date: 04-Feb-2010

* * * Registration Information * * *

Registration: 67702-GR - SLUGKIL MP

Company: 67702 - W. NEUDORFF GMBH KG

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: John Fournier JFOURN01

Sent Date: _____ Calculated Due Date: 12-Jan-2011 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (B630) NEW USE;FIRST FOOD USE;MICROBIAL/BIOCHEMICAL WITH EXEMPTION;

Ingredients: 139114, Sodium ferric ethylenediaminetetraacetate(71.42%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 04-Feb-2010 Due Back: _____

DP Ingredient: 139114, Sodium ferric ethylenediaminetetraacetate

DP Title: _____

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #: _____

	Assigned To	Date In	Date Out		
Organization:	BPPD / BPB			Last Possible Science Due Date:	17-Jan-2010
Team Name:	RM 91			Science Due Date:	27-Aug-2010
Reviewer Name:	Jones, Russell			Sub Data Package Due Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Russ,

Please assign the attached submission for primary and secondary review. This is a sodium ferric EDTA manufacturing-use product for the formulation of slug control products. In addition to the basic formulation, 4 alternate formulations are included. This is a PRIA B630 action. Please ensure secondary review is complete by 8/27/10.

Thanks,

John

Missing 479425 - 12 13 14 15 16

DP#: (373965) *** Studies Sent for Review *** Decision#: (425379)

MRID	MRID Status	Citation Reference	Guideline
47942502		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Preliminary Analysis, Certified Limits and Enforcement Analytical Method. Unpublished study prepared by Eco-Care Technologies, Inc. 23 p.	830.1800/Enforcement analytical method
47942514	Missing	Cordts, R. (2008) Slugkil MP: Toxicology Data - Generic Data: Avian Dietary Toxicity Test (in Birds). Project Number: 21624. Unpublished study prepared by Laboratorium fuer Pharmakologie und Tox. 54 p.	850.2200/Avian dietary toxicity test
47942501		Almond, D. ; Stewart, C. (2009) Slugkil MP: Manufacturing-Use Product: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 19 p.	880.1400/Discussion of formation of impurities
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.6304/Odor
47942517		Talarek, W. (2009) Slugkil MP: Compilation of Toxicology Data. Unpublished study prepared by W. Neudorff GmbH KG. 272 p.	
47942515	Missing	Borrmann, K. (2007) Slugkil MP: Toxicology Data - Generic Data: Acute Toxicity - Rainbow Trout. Project Number: 20071275/01/AAOM. Unpublished study prepared by Eurofins - GAB GmbH. 43 p.	850.1075/Fish acute toxicity test, freshwater and marine
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.6303/Physical state
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7520/Particle size, fiber length, and diameter distribution
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7550/Partition coefficient (n-octanol/water), shake flask method
47942504		Almond, D.; Stewart, C. (2009) Slugkil MP - Generic Data: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 86 p.	880.1400/Discussion of formation of impurities
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7300/Density/relative density
47942501		Almond, D. ; Stewart, C. (2009) Slugkil MP: Manufacturing-Use Product: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 19 p.	880.1200/Description of starting materials, production and formulation process
47942512	Missing	Haferkorn, J. (2008) Slugkil MP: Toxicology Dat - Generic Data: Inhalation (in Rats). Project Number: 21619, NEU05412. Unpublished study prepared by Laboratorium fuer Pharmakologie und Tox. 40 p.	870.1300/Acute inhalation toxicity
47942511		Haferkorn, J. (2007) Slugkil MP: Toxicology Data - Generic Data: Skin Sensitization (in Mice). Project Number: 21622, NEU05412. Unpublished study prepared by Laboratorium fuer Pharmakologie und Tox. 41 p.	870.2600/Skin sensitization
47942505		Stewart, C.; Almond, D. (2009) Slugkil MP - Generic Data: Product Chemistry: Analysis and Certification of Product Ingredients. Unpublished study prepared by Eco-Care Technologies, Inc. 24 p.	830.1700/Preliminary analysis
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.6303/Physical state
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7220/Boiling point/boiling range
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7200/Melting point/melting range
47942504		Almond, D.; Stewart, C. (2009) Slugkil MP - Generic Data: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 86 p.	880.1100/Product identity and composition
47942504		Almond, D.; Stewart, C. (2009) Slugkil MP - Generic Data: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 86 p.	880.1200/Description of starting materials, production and formulation process

MRID	MRID Status	Citation Reference	Guideline
47942518		Talarek, W. (2009) Slugkil MP: Compilation of Environmental Fate Data. Unpublished study prepared by W. Neudorff GmbH KG. 135 p.	
47942500		Neudorff GmbH KG (2009) Submission of Product Chemistry, Toxcicity and Environmental Fate Data in Support of the Applications for Registration of Slugkil MP, Slugkil 5, and Slugkil 2. Transmittal of 18 Studies.	
47942502		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Preliminary Analysis, Certified Limits and Enforcement Analytical Method. Unpublished study prepared by Eco-Care Technologies, Inc. 23 p.	830.1700/Preliminary analysis
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.6313/Stability to sunlight, normal and elevated temperatures, metals, and metal ions
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7220/Boiling point/boiling range
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7950/Vapor pressure
47942505		Stewart, C.; Almond, D. (2009) Slugkil MP - Generic Data: Product Chemistry: Analysis and Certification of Product Ingredients. Unpublished study prepared by Eco-Care Technologies, Inc. 24 p.	830.1800/Enforcement analytical method
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7840/Water solubility: Column elution method, shake flask method
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.6304/Odor
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.6302/Color
47942508		Leuschner, P. (2007) Slugkil MP: Toxicology Data - Generic Data: Acute Dermal Toxicity Study (Limit Test) (in Rats). Project Number: 21618, NEU05412. Unpublished study prepared by Laboratorium fuer Pharmakologie und Tox. 35 p.	870.1200/Acute dermal toxicity
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7050/UV/Visible absorption
47942507		Leuschner, P. (2007) Slugkil MP: Toxicology Data - Generic Data: Acute Oral Toxicity (Limit Test) (in Rats). Project Number: 21617, NEU05412. Unpublished study prepared b: Laboratorium fuer Pharmakologie und Tox. 33 p.	870.1100/Acute Oral Toxicity
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7300/Density/relative density
47942509		Leuschner, J. (2007) Slugkil MP: Toxicology Data - Generic Data: Primary Eye Irritation (in Rabbits). Project Number: 21621, NEU05412. Unpublished study prepared by Laboratorium fuer Pharmakologie und Tox. 36 p.	870.2400/Acute eye irritation
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.6313/Stability to sunlight, normal and elevated temperatures, metals, and metal ions
47942502		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Preliminary Analysis, Certified Limits and Enforcement Analytical Method. Unpublished study prepared by Eco-Care Technologies, Inc. 23 p.	830.1750/Certified limits
47942510		Leuschner, J. (2007) Slugkil MP: Toxicology Data - Generic Data: Primary Dermal Irritation (in Rabbits). Project Number: 21620, NEU05412. Unpublished study prepared by Laboratorium fuer Pharmakologie und Tox. 36 p.	870.2500/Acute dermal irritation
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7520/Particle size, fiber length, and diameter distribution
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7950/Vapor pressure

DP#: (373965) *** Studies Sent for Review *** Decision#: (425379)

MRID	MRID Status	Citation Reference	Guideline
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.6302/Color
47942516	= Missing	Borrmann, K. (2007) Slugkil MP: Toxicology Data - Generic Data: Toxicity - Acute Aquatic Invertebrate, Daphnia. Project Number: 20071275/01/AADM. Unpublished study prepared by Eurofins - GAB GmbH. 44 p.	850.1010/Aquatic invertebrate acute toxicity, test, freshwater daphnids
47942513	Missing	Cordts, R. (2008) Slugkil MP: Toxicology Data - Geaneric Data: Avian Acute Oral Test (in Birds). Project Number: 21623. Unpublished study prepared by Laboratorium fuer Pharmakologie und Tox. 49 p.	850.2100/Avian acute oral toxicity test
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7050/UV/Visible absorption
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7840/Water solubility: Column elution method, shake flask method
47942505		Stewart, C.; Almond, D. (2009) Slugkil MP - Generic Data: Product Chemistry: Analysis and Certification of Product Ingredients. Unpublished study prepared by Eco-Care Technologies, Inc. 24 p.	830.1750/Certified limits
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7000/pH of water solutions or suspensions
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7000/pH of water solutions or suspensions
47942503		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 26 p.	830.7200/Melting point/melting range
47942506		Stewart, C.; Almond, D. (2009) Slugkil MP: Product Chemistry - Generic Data: Physical and Chemical Characteristics. Unpublished study prepared by Eco-Care Technologies, Inc. 27 p.	830.7550/Partition coefficient (n-octanol/water), shake flask method
47942501		Almond, D. ; Stewart, C. (2009) Slugkil MP: Manufacturing-Use Product: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 19 p.	880.1100/Product identity and composition

S: 903085

Material Sent for Data Extraction

Reg. No. 67702-31

Description: Final Printed Label

☒ **Material(s) Sent to Data Extraction contractors:**

- ☐ Newly stamped accepted label Dated:____
- ☐ Notification Dated:____
- ☐ New CSF Dated:____
- ☒ Other: FPL

☒ **Decision #:** 454502

☐ **Other Action/Comments:**_____

File this coversheet and attach materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the Jacket with the coversheet and materials inside, to Staff in the Information Services Center(ISC) (Room S-4900) or place in the designated bin. If the Jacket is full or only available as an image, please file materials in a new jacket cover follow the same procedure as above. For further information, please call 703-605-0716.

Reviewer's Name: Sylvester George

Phone: 703-603-0688 **Division:** BPPD

Date: 10/21/2011

Created September 28, 2011
Closed

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: **CAUTION.** Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, and using the toilet. Remove and wash contaminated clothing before reuse.

Environmental Hazards: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

WARRANTY

To the extent consistent with applicable law, the seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with the directions for use. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. To the extent consistent with applicable law, seller makes no other warranties, either expressed or implied.

GENERAL INFORMATION (WHY SLUG AND SNAIL BAIT IS EFFECTIVE)

This product has a non-toxic mode of action and can be used in areas where pet and wildlife protection is a concern. When slugs and snails ingest the bait, they stop feeding and crawl back to their shelter where they eventually die. It remains effective under varying weather and environmental conditions.

The bait is ingested by slugs and snails when they travel from their hiding places to plants. Ingestion, even in small amounts, will cause them to cease feeding. This physiological effect of the bait gives immediate protection to the plants even though the slugs and snails may remain in the area. After eating the bait, the slugs and snails cease feeding, become less mobile and begin to die within three to six days. Dead slugs and snails may not be visible as they often crawl away to secluded places to die. Plant protection will be observed in the decrease in plant damage.

This product is effective against a wide variety of slugs and snails and will give protection to home lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits, berries, citrus, crop and seed plants. The bait can be scattered on the lawn or on the soil around any vegetable or seed crops, flowers or fruit trees or bushes to be protected.

Complies with EPA Accepted Labeling

Date: [illegible] 2011

Reviewer [illegible] George

FERROXX MP

Active Ingredient:	By weight
Sodium Ferric EDTA.....	71.42%
Other Ingredients:	28.58%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 67702-31 EPA Est. No. 67702-DEU-1

NET CONTENTS

FIRST AID

If swallowed: Call a poison control center or doctor immediately for treatment advice.Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Hotline Number

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticide Information Center at 1-800-858-7378 seven days a week, 6:30 am to 4:30 Pacific Time (NPIC Web site: www.npic.orst.edu). During other times, call the poison control center at 1-800-222-1222.

See Side Panel for Precautionary Statements.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is designed for use in the manufacturing or formulating of end-use pesticide products for use in controlling and killing slugs and snails for the terrestrial food and non-food crop, greenhouse food and non-food crop, and residential outdoor general use patterns as follows: (1) residential sites home gardens including vegetables, fruits including citrus, berries, and herbs, outdoor ornamentals, greenhouses and lawns; and (2) commercial and agricultural sites including vegetables, fruits including citrus, berries, herbs, field crops, artichokes, outdoor ornamentals, greenhouses, outdoor container-grown nursery plants, commercial turf, sod, golf courses, and grass buffers around gardens, crop areas and ornamentals, grass grown for seed production and cereal crops (such as wheat, barley, oats and rye), and non-crop areas including parks, fallow land, barrier strips, and buffer zones around agricultural crop areas. Those persons using this product to manufacture or formulate pesticide products are responsible for the registration of their products with the Environmental Protection Agency prior to marketing. This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty metal drum, plastic bag, box or plastic tote into application equipment. Then dispose of empty metal drum, plastic bag, box or plastic tote in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

BATCH CODE

Registrant: W. Neudorff GmbH KG, Postfach 1209, An der Mühle 3, 31860 Emmerthal, Germany
Phone: 250-652-5888
www.neudorff.com

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: CAUTION. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, and using the toilet. Remove and wash contaminated clothing before reuse.

Environmental Hazards: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

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NEUDORFF®

FERROXX MP

Active Ingredient:	By weight
Sodium Ferric EDTA.....	71.42%
Other Ingredients:	28.58%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 67702-31 EPA Est. No. 67702-DEU-1

NET CONTENTS

FIRST AID

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If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

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See Side Panel for Precautionary Statements.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is designed for use in the manufacturing or formulating of end-use pesticide products for use in controlling and killing slugs and snails for the terrestrial food and non-food crop, greenhouse food and non-food crop, and residential outdoor general use patterns as follows: (1) residential sites home gardens including vegetables, fruits including citrus, berries, and herbs, outdoor ornamentals, greenhouses and lawns; and (2) commercial and agricultural sites including vegetables, fruits including citrus, berries, herbs, field crops, artichokes, outdoor ornamentals, greenhouses, outdoor container-grown nursery plants, commercial turf, sod, golf courses, and grass buffers around gardens, crop areas and ornamentals, grass grown for seed production and cereal crops (such as wheat, barley, oats and rye), and non-crop areas including parks, fallow land, barrier strips, and buffer zones around agricultural crop areas. Those persons using this product to manufacture or formulate pesticide products are responsible for the registration of their products with the Environmental Protection Agency prior to marketing. This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty metal drum, plastic bag, box or plastic tote into application equipment. Then dispose of empty metal drum, plastic bag, box or plastic tote in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

BATCH CODE

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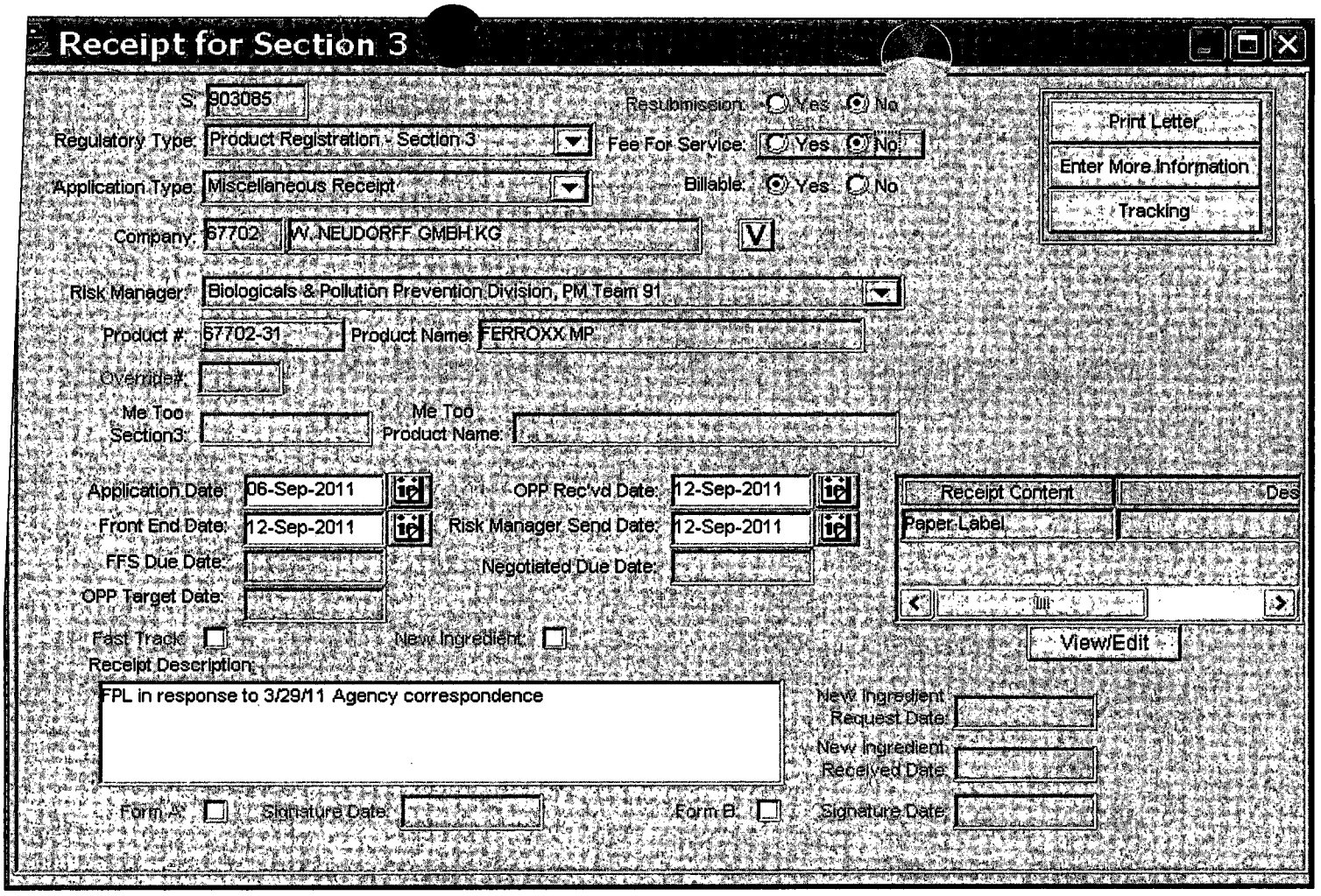
Phone: 250-652-5888
www.neudorff.com



Recvd 9/12/11 AB

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Ferroxx MP	Linda Hollis	[x] None [ ] Restricted
4. Company/Product (Name) 67702-31	**PM#** 91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [x] Final printed labels in response to Agency letter dated March 29, 2011
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Walter G. Talarek	Authorized Agent	
4. Typed Name Walter G. Talarek	**5. Date** September 6, 2011	

PRECAUTIONARY STATEMENTS

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NEUDORFF®

FERROXX MP

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Other Ingredients:	28.58%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 67702-31 EPA Est. No. 67702-DEU-1

NET CONTENTS

FIRST AID

If swallowed: Call a poison control center or doctor immediately for treatment advice.Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Hotline Number

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticide Information Center at 1-800-858-7378 seven days a week, 6:30 am to 4:30 Pacific Time (NPIC Web site: www.npic.orst.edu). During other times, call the poison control center at 1-800-222-1222.

See Side Panel for Precautionary Statements.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is designed for use in the manufacturing or formulating of end-use pesticide products for use in controlling and killing slugs and snails for the terrestrial food and non-food crop, greenhouse food and non-food crop, and residential outdoor general use patterns as follows: (1) residential sites home gardens including vegetables, fruits including citrus, berries, and herbs, outdoor ornamentals, greenhouses and lawns; and (2) commercial and agricultural sites including vegetables, fruits including citrus, berries, herbs, field crops, artichokes, outdoor ornamentals, greenhouses, outdoor container-grown nursery plants, commercial turf, sod, golf courses, and grass buffers around gardens, crop areas and ornamentals, grass grown for seed production and cereal crops (such as wheat, barley, oats and rye), and non-crop areas including parks, fallow land, barrier strips, and buffer zones around agricultural crop areas. Those persons using this product to manufacture or formulate pesticide products are responsible for the registration of their products with the Environmental Protection Agency prior to marketing. This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty metal drum, plastic bag, box or plastic tote into application equipment. Then dispose of empty metal drum, plastic bag, box or plastic tote in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

BATCH CODE

Registrant: W. Neudorff GmbH KG, Postfach 1209, An der Mühle 3, 31860 Emmerthal, Germany
Phone: 250-652-5888
www.neudorff.com

MATERIAL TO BE ADDED TO JACKET

REG #: 67702-31

Description: new registration

if applicable, check all that are attached:		
☒	new stamped accepted label	Send to CSC
☒	new CSF	
☐	notification	
☐	other:	

Instructions:
Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: John Fournier Date: 3/31/2011

Phone: (703) 308-0169 Division: BPPD

UNITED S[illegible]ES ENVIRONMENTAL PROTECTION A[illegible]CY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:	Date of Issuance:
67702-31	MAR 29 2011
Term of Issuance:	UNCONDITIONAL
Name of Pesticide Product:	Ferroxx MP

NOTICE OF PESTICIDE:

__X___ Registration ____ Re-registration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, Virginia 22066

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, **"EPA Reg. No. 67702-31".**

3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

   If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

W. Michael McDavit

Date: MAR 29 2011

W. Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division

CONCURRENCES						
SYMBOL	7511P					
SURNAME	Fournier					
DATE	29 Mar 11					

EPA Form 8570-6

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

FERROXX MP

For Manufacturing and Formulating Use

ACCEPTED

MAR 29 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 67702-31

Active Ingredient:	By weight
Sodium Ferric EDTA.....	71.42%
Other Ingredients:	28.58%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT: 20lbs, 25lbs, 40lbs, 45lbs, 50lbs, 55lbs (25 kg), 1984lbs (900 kg), 2011lbs (912 kg), 2116 lbs (960kg)

FIRST AID

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Hotline Number

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: **CAUTION**. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, and using the toilet. Remove and wash contaminated clothing before reuse.

Environmental Hazards: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is designed for use in the manufacturing or formulating of end-use pesticide products for use in controlling and killing slugs and snails for the terrestrial food and non-food crop, greenhouse food and non-food crop, and residential outdoor general use patterns as follows: (1) residential sites home gardens including vegetables, fruits including citrus, berries, and herbs, outdoor ornamentals, greenhouses and lawns; and (2) commercial and agricultural sites including vegetables, fruits including citrus, berries, herbs, field crops, artichokes, outdoor ornamentals, greenhouses, outdoor container-grown nursery plants, commercial turf, sod, golf courses, and grass buffers around gardens, crop areas and ornamentals, grass grown for seed production and cereal crops (such as wheat, barley, oats and rye), and non-crop areas including parks, fallow land, barrier strips, and buffer zones around agricultural crop areas. Those persons using this product to manufacture or formulate pesticide products are responsible for the registration of their products with the Environmental Protection Agency prior to marketing. This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty metal drum, plastic bag, box or plastic tote into application equipment. Then dispose of empty metal drum, plastic bag, box or plastic tote in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

BATCH CODE

WARRANTY

To the extent consistent with applicable law, the seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with the directions for

use. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. To the extent consistent with applicable law, seller makes no other warranties, either expressed or implied.

[The following claims and product information may or may not be presented on the product's label and labeling:
- The active ingredient in this product is exempt from the requirement for a tolerance when used as a molluscicide in or on all food commodities.
-US Patent Number 5,437,870
-Ferroxx is a (registered) trademark of (W.)Neudorff (GmbH KG)
-Made with Ferroxx®(™)
-Manufactured under a license of W. Neudorff GmbH KG, Germany.

NEUDORFF® 1

EPA Registration #67702- 31 **EPA Establishment #**

Registrant: W. Neudorff GmbH KG
Postfach 1209, An der Mühle 3,
31860 Emmerthal, Germany
Phone: 250-652-5888
www.neudorff.com

Memorandum

Date: 11/30/10

To: PM 91, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Administrative Materials

Please read instructions on reverse before completing form. Form Approved OMB No. 2070-0060 Print Form

United States Environmental Protection Agency Washington, DC 20460

EPA

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702-GR	Linda Hollis	☒ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Slugkil MP	91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Resubmission requesting waiver of fish acute toxicity data requirement and responding to Mr. John Fournier's e-mail of November 10, 2010, on MRID 47942515, and changing product's brand name to FERROXX MP. See the enclosed letter to Ms. Linda Hollis, PM 91, for a full explanation of the resubmission.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
[signature]	Authorized Agent	(Stamped)
4. Typed Name	**5. Date**	
Walter G. Talarek	November 19, 2010	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 29, 2010

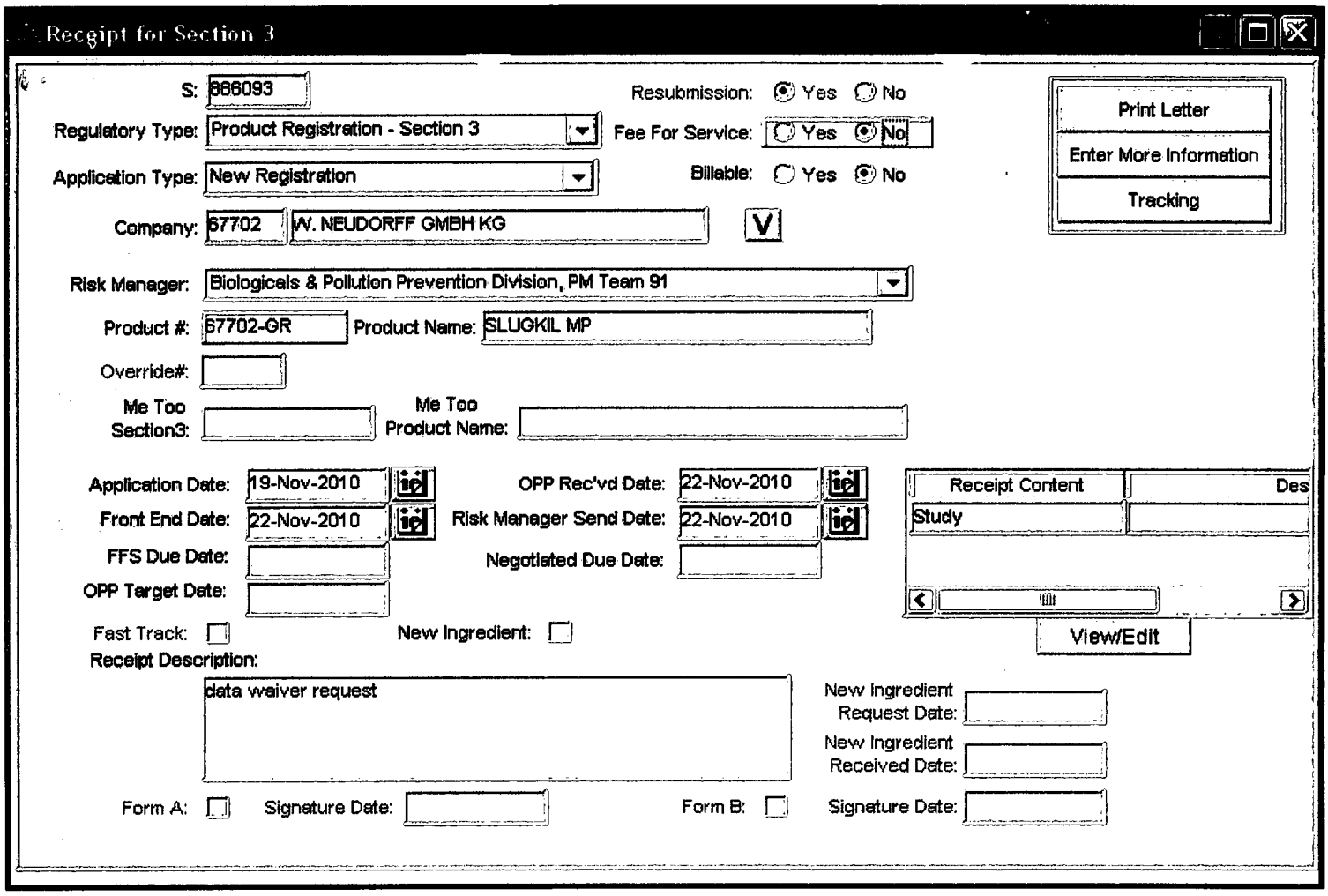
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

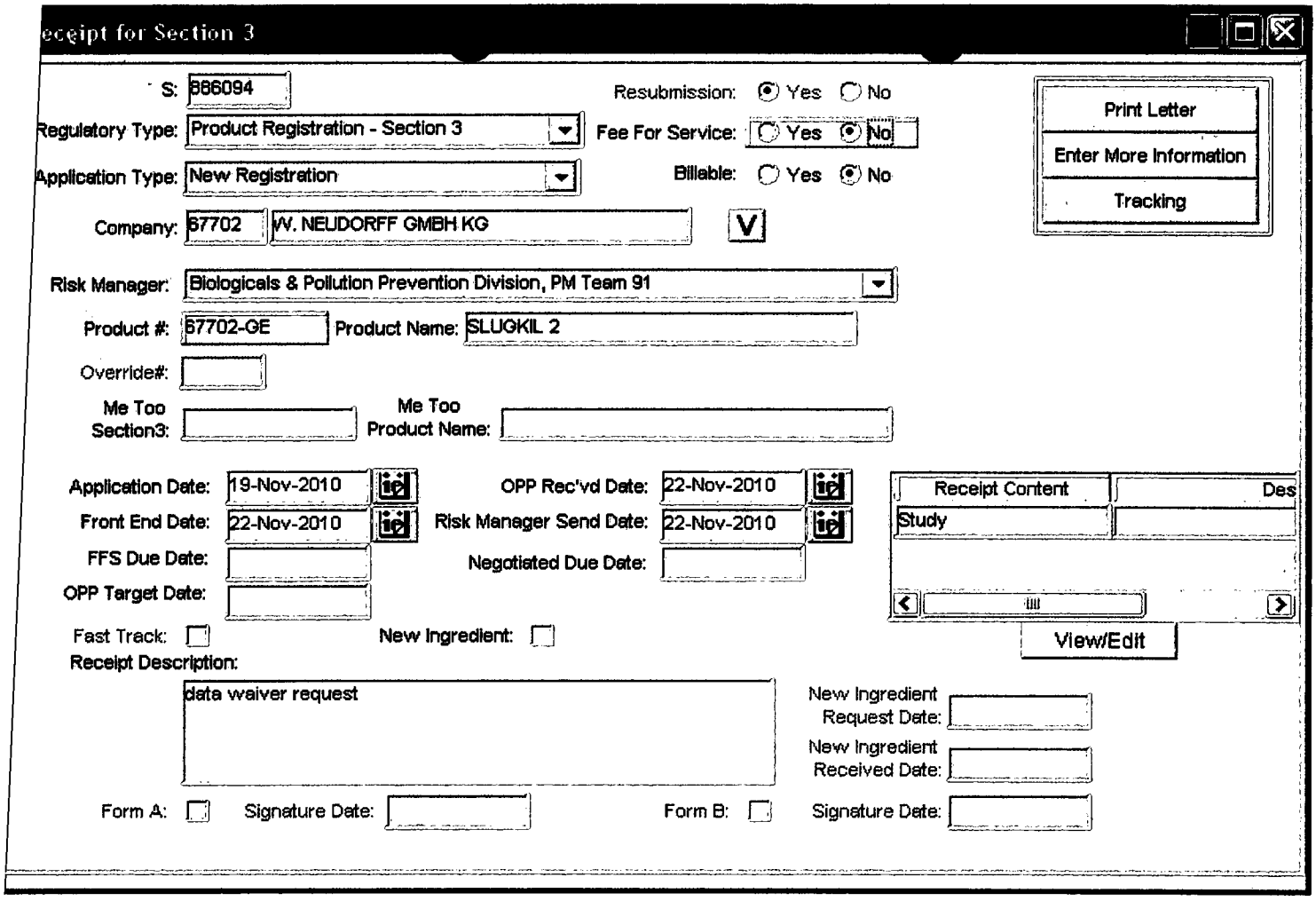
W. NEUDORFF GMBH KG
POSTFACH 1209
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

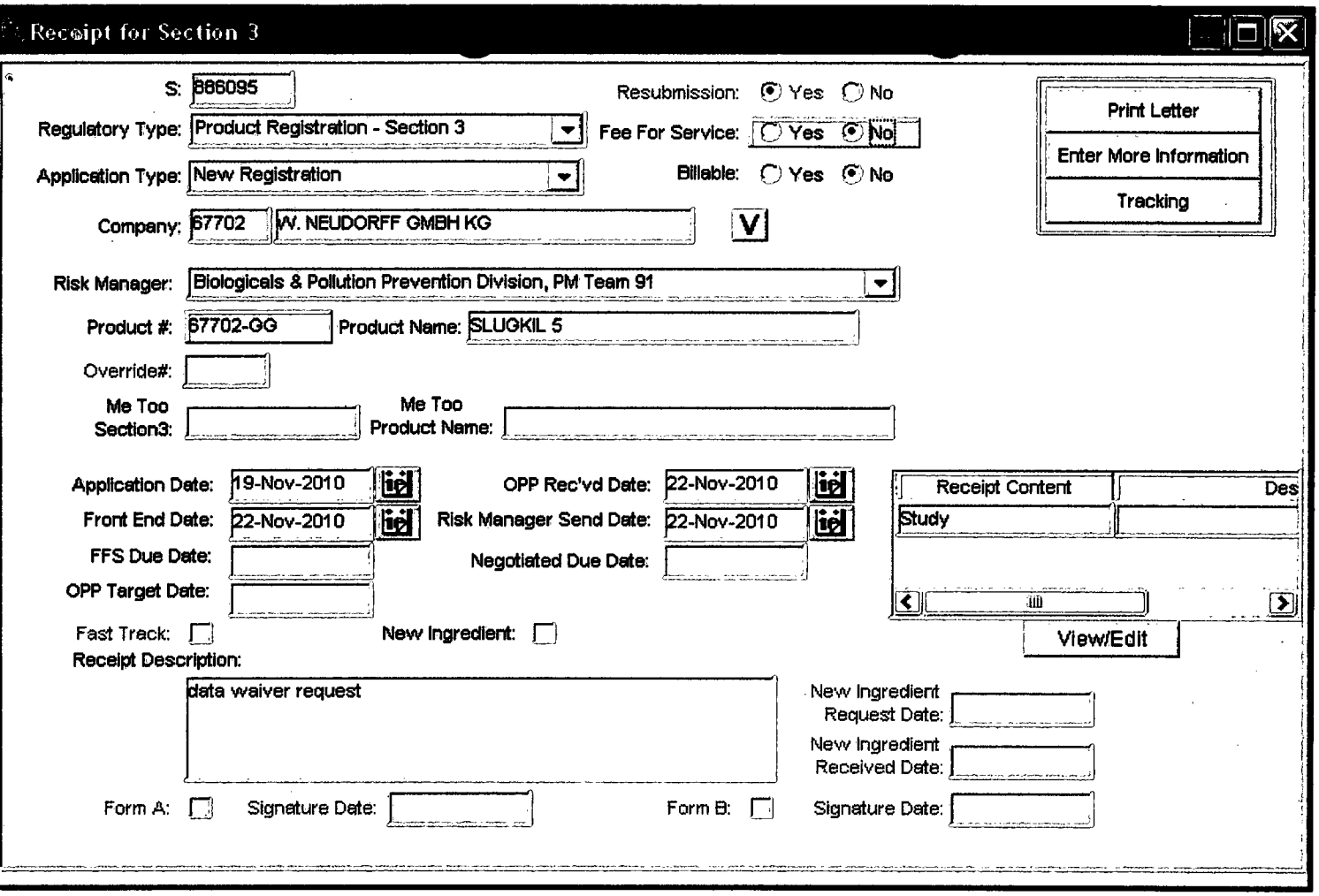
Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 22-NOV-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Recgipt for Section 3
S: 886093
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 67702 W. NEUDORFF GMBH KG
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GR
Product Name: SLUGKIL MP
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 19-Nov-2010
OPP Rec'vd Date: 22-Nov-2010
Front End Date: 22-Nov-2010
Risk Manager Send Date: 22-Nov-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
data waiver request
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:


eceipt for Section 3
S: 886094
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 67702 W. NEUDORFF GMBH KG
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GE
Product Name: SLUGKIL 2
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 19-Nov-2010
OPP Rec'vd Date: 22-Nov-2010
Front End Date: 22-Nov-2010
Risk Manager Send Date: 22-Nov-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
data waiver request
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date: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S: 886095
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 67702 W. NEUDORFF GMBH KG
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GG
Product Name: SLUGKIL 5
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 19-Nov-2010
OPP Rec'vd Date: 22-Nov-2010
Front End Date: 22-Nov-2010
Risk Manager Send Date: 22-Nov-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
data waiver request
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

November 19, 2010

DELIVERED BY COURIER
Linda Hollis, Chief
Biopesticides Branch
Biopesticides and Pollution Prevention Division
c/o Document Processing Desk (7504P)
Office of Pesticide Programs
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Applications for Registration of Slugkil MP, Slugkil 2 and Slugkil 5
EPA File Symbol 67702-GR, 67702-GE and 67702-GG
Miscellaneous Submission – Data Waiver Request for OPPTS 850.1075

Dear Ms. Hollis:

By this letter, W. Neudorff GmbH KG ("Neudorff") requests a waiver of the requirement for a fish acute toxicity, freshwater, study, OPPTS Guideline 850.1075, to support its applications for registration of Slugkil MP, EPA File Symbol 67702-GR, Slugkil 2, EPA File Symbol 67702-GE, and Slugkil 5, EPA File Symbol 67702-GG. In support of this request, Neudorff offers the following reasons.

First, EPA has granted a waiver of the data requirement for Safer, Inc.'s ("Safer's") Slug and Snail Killer Product, EPA Reg. No. 42697-61. The Safer product contains the same active ingredient as the active ingredient in the Slugkil products, i.e., ferric sodium EDTA. In applying for its registration, Safer requested a waiver of the fish acute toxicity, freshwater, data requirement, and EPA granted the waiver for the following reasons: "There have been no reported effects of sodium ferric EDTA on vertebrates having iron-based blood systems. Consequently, field application of sodium ferric EDTA at label rates recommended on product label should present no risk to vertebrate animals such as birds and fish. Additionally, exposure of fish should not occur when label directions are followed, as the product is a pelleted bait applied directly to the soil". See pages 3 and 10 of the enclosed "Science Review to support registration of new food-use product, Slug and Snail Killer (EPA Reg. No. 42697-AR), containing 6.00% w/w ferric sodium EDTA (PC code: 139114) as its active ingredient. DP Barcode: DP 316206. Decision No. 352633", which is dated February 7, 2009 (Enclosure 1).

Also, see page 2 of 2 of EPA's Sodium Ferric EDTA (PC Code 139114) Fact Sheet and page 12 of 17 of EPA's Biopesticides Registration Action Document ("BRAD") [for] Sodium Ferric EDTA (PC Code 139114)

for EPA's rationale why this data requirement was waived. The Fact Sheet states that the data requirement was waived because "the waivers rationales that were provided showed little or no toxicity to non-target organisms". The BRAD states that:

> "The blood of vertebrate animals contains hemoglobin, which is iron-based, rather than copper-based hemocyanin. There have been no reported effects of sodium Ferric EDTA on vertebrates having iron-based blood systems. Since both birds and fish are vertebrate animals, field application of Sodium Ferric EDTA at label rates should present little or no risk from ingestion of the end use product pellets. Additionally, exposure of fish should not occur when label directions are followed, as the end use product is applied directly to soil, and is not intended for use in aquatic environments." Id.

Neudorff submits that this waiver rationale should also apply to its Slugkil products because the products are pelleted baits, which contain the active ingredient at smaller percentages, i.e., 5% and 2%, than the Safer product, i.e., 6%, and which are applied to the soil at approximately the same application rates as the Safer product, and little or no toxicity to non-target organisms is expected because fish are vertebrates with iron-based blood systems.

Second, Neudorff is hereby citing a fish acute toxicity, freshwater, study that it submitted previously in support of its application for registration of NEU1173H, EPA Reg. No. 67702-26, and that EPA classified as "Acceptable". See the Data Evaluation Record for MRID 47233002 (Enclosure 2). This study was conducted on the Rainbow trout. Ferric HEDTA is very similar in chemical structure to ferric sodium EDTA. See Enclosure 3. Neudorff is requesting that EPA bridge from the results of this study to what would be expected had the study been conducted on one of the Slugkil products. NEU1173H contains the active ingredient ferric HEDTA at 26.52%, while Slugkil MP, Slugkil 2 and Slugkil 5 contain ferric sodium EDTA at 71.42%, 2% and 5%, respectively.

Third, Neudorff would like to draw your attention to Canada's Pest Management Regulatory Agency's ("PMRA's") Proposed Registration Decision [on] Ferric Sodium EDTA (PRD2007-13) and Registration Decision on Ferric Sodium EDTA (RE2008-04). See Enclosures 4 and 5. In PMRA's proposed decision, in addressing the pesticide's effects on aquatic organisms, PMRA stated "No data were submitted by the registrant addressing potential toxic effects of ferric sodium EDTA on aquatic organisms (invertebrates, fish, plants). While ferric sodium EDTA is expected to be toxic to aquatic organisms with haemocyanin blood systems, such as daphnia, crabs, crayfish, lobsters and shrimp, it is expected to pose negligible risk under conditions of field use, as there is negligible potential for exposure". Id. 15. In the registration decision, PMRA stated "Ferric sodium EDTA is expected to pose negligible risk to terrestrial and aquatic organisms under conditions of use". Id. 4.

Last, should EPA decide that a waiver is not appropriate for the subject study, please note that Neudorff has contacted the test laboratory that conducted the acute fish toxicity, freshwater, study on Slugkil MP, i.e., MRID 47942515, the laboratory has amended the study to address three of the eight EPA reviewer's comments concerning the study that were contained in John Fournier's e-mail of November 10, 2010, to me, and Neudorff is submitting the amended study with this letter. The amended study addresses Comment Nos. 2, 5 and 6. With regard to Comment Nos. 1, 3, 4 and 8, the test laboratory's study director offered the following answers:

> **Comment 1** – According to the description in the method, there is no need for the vapor pressure and hydrolysis rate at different pHs for this test. There were no mortalities found, and

as described at page 16 of the report, they found 98.8% of the material, so there was less effect by vapor pressure or hydrolysis.

Comment 3 – The tank used for the tests is made of stainless steel, which is described at page 11 of the report (point 4.4).

Comment 4 – As described also at page 11 of the report (4.5.1), they used dechlorinated drinking water and deionized water for breeding and also for testing the fish.

Comment 8 – According to OECD, it is required to have 7 fish in one test, but they used more, i.e., 10 fish. The OPPTS guideline states that it is "preferred" to have two replicates, but the two replicates are not required. The main reason for the replicates is to be able to explain indefinite effects or unclear results. But in this study, the effects and results are totally clear, i.e., no mortalities and no other effects. Therefore, and according to the European requirements to avoid animal testing, it is unacceptable to test more animals than needed. This is also the reason why the lab would not be allowed to repeat the test.

With regard to Comment No. 7, where the EPA reviewer stated that that the study was incomplete because there was no test with the bluegill sunfish (warm water species), please note that EPA's data requirements regulations for biochemicals only require testing on one freshwater coldwater species. See 40 CFR § 158.2060(e), Footnote 4. Therefore, the bluegill sunfish data requirement is inapplicable to the Slugkil products.

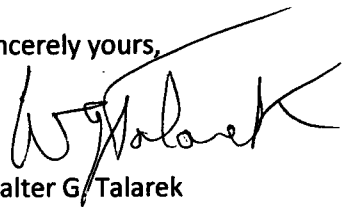
New generic Data Matrices (EPA Forms 8570-35) and Certifications with Respect to Citation of Data (EPA Forms 8580-34) for the three Slugkil products are enclosed. Please note that the only differences between these forms and the forms submitted with the application for registration are (1) the dates are different and (2) the MRID for the study on NEU1173H, EPA Reg. No. 67702-26, i.e., MRID 47233003, has been inserted in the Data Matrices.

I have discussed this data waiver request with Mr. John Fournier of your staff.

Last, Neudorff would like to revise the brand name for this product to FERROX MP. Five (5) copies of the amended label showing this brand name are enclosed.

Please feel free to contact me if you have any questions.

Sincerely yours,



Walter G. Talarek

Enclosures

Cc: John Fournier

TRANSMITTAL DOCUMENT

1. Name and address of submitter

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

2. Regulatory action in support of which this package is submitted

Resubmission in support of application for registration of Slugkil MP, EPA File Symbol 67702-GR, and in response to Data Evaluation Record on MRIDs 47942501-06

3. Transmittal date

November 19, 2010

4. List of submitted studies

	Volume 1	Administrative Materials EPA Form 8570-1 Letter to Ms. Hollis explaining resubmission Enclosure 1to Letter to Ms. Hollis – Science Review to support registration of new food-use product, Slug and Snail Killer (EPA Reg. No. 42697-AR), containing 6.00 % w/w ferric sodium EDTA (PC code: 139114) as its active ingredient. BP Barcode: DP 316206. Decision No. 352633. Enclosure 2 to Letter to Ms. Hollis – Data Evaluation Record; NEU1173H (iron HEDTA); Study Type: Freshwater Fish Acute Toxicity (OPPTS 850.1075); MRID 47233002 Enclosure 3 to Letter to Ms. Hollis – Chemical Similarity FeHEDTA and FeEDTA Enclosure 4 to Letter to Ms. Hollis – PMRA PRD2007-13; Proposed Registration Decision; Ferric Sodium EDTA Enclosure 5 to Letter to Ms. Hollis - PMRA RD2008-04; Registration Decision; Ferric Sodium EDTA Labels (5 copies) Certification with Respect to Citation of Data (EPA Form 8570-34) Data Matrix (EPA Form 8570-35)
48299701	Volume 16	Fish Acute Toxicity - Rainbow Trout; Amendment No. 1 to Study (OPPTS 850.1075)

Company Official: Walter G. Talarek
Authorized Agent

Signature

Company Name:	W. Neudorff GmbH KG	
Company Contact:	Walter G. Talarek Name	(703) 759-4837 Phone

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JAN 04 2011

Walter G. Talarek
Agent for W. Neudorff GmbH KG
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

Subject: Slugkil MP, Slugkil 2, Slugkil 5 (EPA File Symbols 67702-GR, -GE, and -GG), and Petition # 9F7668
PRIA Code B630 due 1/12/2011
Application Dated: January 20, 2010
Decision #s: 425379, 425381, 425380, and 425382

Dear Mr. Talarek:

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the application referred to above, submitted in connection with registration under FIFRA section 3(c)(5). BPPD has concluded your application is **not** acceptable, and that deficiencies **must** be addressed.

Your original submissions for the applications referred to above were found to be deficient. Deficiencies identified by Agency review were communicated to you on November 10, 2010. You responded to these deficiencies by resubmitting the applications on November 22, 2010 with corrections. Review of your resubmitted applications was completed by the Agency on December 21, 2010. All of the submitted applications were found to be acceptable. No additional data are needed to meet the requirements for registration.

At this time, however, insufficient time remains in the PRIA review period to allow the Agency to make a regulatory decision. The Agency must also allow a public comment period on the proposed tolerance exemption rule for your active ingredient, Sodium Ferric EDTA. As such, the PRIA due date will need to be renegotiated.

CONCURRENCES

SYMBOL	7511P							
SURNAME	Fournier							
DATE	4 Jan 10							

BPPD did not perform a label review because the application is deficient. When the deficiencies listed above are addressed and satisfied, BPPD will then proceed with a thorough label review and inform you of any label revisions that may be required. At this time, the Agency considers your application to be deficient. As described, BPPD cannot proceed with a review of the application until you successfully address all deficiencies identified in this letter. If you choose to proceed with the above referenced application, the Agency will need to renegotiate the PRIA II due date. Based on the deficiencies outlined in this letter, the Agency will require additional time to make a regulatory decision and allow public comment.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA II) guaranteed you a regulatory decision for the action category B630 of twelve months and a decision due date of January 12, 2011. By regulation, the Agency is obligated to give you 75 days (40 CFR § 152.105) in which to address the deficiencies identified above. If we do not hear from you within 75 days from the date of letter (March 20, 2011), the Agency can administratively withdraw your application from further consideration without notice to you. Alternatively, you may withdraw the application and resubmit when you have all the information, or the Agency will issue a can not grant latter under PRIA. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application.

If the Agency does issue a letter stating it cannot grant your application under PRIA II and you submit the required information within 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time frame. Please contact the regulatory action leader, John Fournier, at (703) 308-0169 or via email at fournier.john@epa.gov immediately with your response.

Sincerely,

Linda A. Hollis, Chief,
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

APPLICATION FOR REGISTRATION OF SLUGKIL MP

Manufacturing-Use Product
EPA Registration Number 67702-GR

CORRESPONDENCE DOCUMENT: EXPLANATIONS AND WAIVER REQUESTS

DATA REQUIREMENTS

40 CFR Parts 152 and 158

AUTHOR

Walter G. Talarek

STUDY REVISED ON

September 21, 2010

STUDY SUBMITTED BY

W. Neudorff GmbH KG
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STUDY PERFORMED BY

Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

Eco-Care Technologies, Inc.
8233 Thompson Place
Saanichton, British Columbia V8M 1S1
Canada

STUDY NUMBER

None

CORRESPONDENCE DOCUMENT: EXPLANATIONS AND WAIVER REQUESTS

Generic Data

Product Chemistry – OPPTS Series 880 and 830

Product identity and composition (OPPTS 880.1100)

Data submitted with application for registration.

Description of materials used to produce product (OPPTS 880.1200)

Data submitted with application for registration.

Description of formulation process (OPPTS 880.1200)

Data submitted with application for registration.

Discussion of formation of impurities (OPPTS 880.1400)

Data submitted with application for registration.

Preliminary analysis (OPPTS 830.1700)

Data submitted with application for registration.

Certified limits (OPPTS 830.1750)

Data submitted with application for registration.

Enforcement analytical method (OPPS 830.1800)

Data submitted with application for registration.

Color (OPPTS 830.6302)

Data submitted with application for registration.

Physical state (OPPTS 830.6303)

Data submitted with application for registration.

Odor (OPPTS 830.6304)

Data submitted with application for registration.

Stability (OPPTS 830.6313)

Data submitted with application for registration.

pH (OPPTS 830.7000)

Data submitted with application for registration.

UV/visible light absorption (OPPTS 830.7050)

Data submitted with application for registration.

Melting point/melting range (OPPTS 830.7200)

Data submitted with application for registration.

Boiling point/boiling range (OPPTS 830.7220)

This requirement is not applicable, because the product is not a liquid.

Density/relative density/bulk density (OPPTS 830.7300)

Data submitted with application for registration.

Dissociation constant(OPPTS 830.7370)

Data submitted with application for registration.

Particle size, fiber length and diameter distribution (OPPTS 830.7520)

Data submitted with application for registration.

Partition coefficient (OPPTS 830.7550, 7560 or 7570)

Data submitted with application for registration.

Water solubility (OPPTS 830.7840)

Data submitted with application for registration.

Vapor pressure (OPPTS 830.7950)

Data submitted with application for registration.

Nontarget Organisms and Environmental Fate – OPPTS Series 850

Aquatic invertebrate acute toxicity, freshwater (OPPTS 850.1010)

Data submitted with application for registration.

Fish acute toxicity, freshwater (OPPTS 850.1075)

Data submitted with application for registration.

Avian acute oral toxicity (OPPTS 850.2100)

Data submitted with application for registration.

Avian dietary toxicity (OPPTS 850.2200)

Data submitted with application for registration.

Terrestrial plant toxicity, seedling emergence (OPPTS 850.4100)

Waiver requested. In the Biopesticides Registration Action Document for Sodium Ferric EDTA (November 20, 2008) ("BRAD"), this requirement was waived because "EDTA is used in specialty fertilizers to chelate inorganic sources of iron and other elements. In soil, EDTA is eventually degraded through microbial activity, and the cations released as a result act as inorganic ions. Tomato plants grown for 130 days in hydroponic solution containing ^{14}C-labelled EDTA contained ^{14}C-labelled amino acids in addition to the ^{14}C-EDTA, indicating EDTA was slowly decomposed by the plants (Matsuda, 1968). In another study using tomato plants grown in solution containing labeled iron chelate (^{59}Fe-^{14}C-EDTA), Hill-Cottingham and Lloyd-Jones (1961) reported that nearly all the iron, and only about 60% of the EDTA, was recovered after 24 days, indicating that the EDTA was decomposed by the plants. No phytotoxic effects were reported in this study". *Id.* at 12 of 17.

Terrestrial plant toxicity, vegetative vigor (OPPTS 850.4150)

Waiver requested. In the Biopesticides Registration Action Document for Sodium Ferric EDTA (November 20, 2008) ("BRAD"), this requirement was waived because "EDTA is used in specialty fertilizers to chelate inorganic sources of iron and other elements. In soil, EDTA is eventually degraded through microbial activity, and the cations released as a result act as inorganic ions. Tomato plants grown for 130 days in hydroponic solution containing ^{14}C-labelled EDTA contained ^{14}C-labelled amino acids in addition to the ^{14}C-EDTA, indicating EDTA was slowly decomposed by the plants (Matsuda, 1968). In another study using tomato plants grown in solution containing labeled iron chelate (^{59}Fe-^{14}C-EDTA), Hill-Cottingham and Lloyd-Jones (1961) reported that nearly all the iron, and only about 60% of the EDTA, was recovered after 24 days, indicating that the EDTA

was decomposed by the plants. No phytotoxic effects were reported in this study". *Id.* at 12 of 17.

Non-target insect testing (OPPTS 850.4350)

Waiver requested. The BRAD stated that this data requirement was waived. *Id.* at 16 of 17. Apparently, the reason for this was "[d]ue to the selectivity of Sodium Ferric EDTA for copper-based blood systems, effects on non-target insects are not expected". *Id.* at 12 of 17. In addition, Neudorff is citing a study conducted on its NEU1173H product, EPA Reg. No. 67702-26, which contains the active ingredient iron HEDTA at 26.52%. See MRID 47233004. This study showed that the LD_{50}/24h and LD_{50}/48h for oral and contact toxicities, were >100.0 and >100.0 and 96.58 and >100.0, respectively. Because of the similarity in chemical structure between FeHEDTA and FeNaEDTA, Neudorff requests that EPA bridge from the results of this study to what would be expected had the study been conducted on FeNaEDTA.

Residue OPPTS Series 860

Chemical identity (OPPTS 860.1100)

Data submitted with application for registration of Slugkil MP. See Volume 5 of the submission.

Directions for use (OPPTS 860.1200)

Data submitted with applications for registration of Slugkil 2 and Slugkil 5. See these products' labels.

Nature of the residue in plants (OPPTS 860.1300)

A waiver is requested for this data requirement based on this pesticide chemical's (1) low toxicity and risks, as discussed in EPA's BRAD on sodium ferric EDTA and PMRA's proposed and final registration decisions on ferric sodium EDTA (PRD2007-13 and RD2008-04), (2) metabolism of the chemical by mammals, (3) the end-use products' physical state as a dry, solid pellet, (4) the chemical's use as a source of dietary iron for food fortification purposes in the US and approval by the World Health Organization for the same purpose, (4) the chemical's environmental fate, (5) the chemical's use pattern and (6) the chemical's use as a liquid fertilizer for counteracting iron deficiency in plants.

Residue analytical method (OPPTS 860.1340)

A waiver is requested for this data requirement based on this pesticide chemical's (1) low toxicity and risks, as discussed in EPA's BRAD on sodium ferric EDTA and PMRA's proposed and final registration decisions on ferric sodium EDTA (PRD2007-13 and RD2008-04), (2) metabolism of the chemical by mammals, (3) the end-use products' physical state as a dry, solid pellet, (4) the chemical's use as a source of dietary iron for

food fortification purposes in the US and approval by the World Health Organization for the same purpose, (4) the chemical's environmental fate, (5) the chemical's use pattern and (6) the chemical's use as a liquid fertilizer for counteracting iron deficiency in plants.

Crop field trials (OPPTS 860.1500)

A waiver is requested for this data requirement based on this pesticide chemical's (1) low toxicity and risks, as discussed in EPA's BRAD on sodium ferric EDTA and PMRA's proposed and final registration decisions on ferric sodium EDTA (PRD2007-13 and RD2008-04), (2) metabolism of the chemical by mammals, (3) the end-use products' physical state as a dry, solid pellet, (4) the chemical's use as a source of dietary iron for food fortification purposes in the US and approval by the World Health Organization for the same purpose, (4) the chemical's environmental fate, (5) the chemical's use pattern and (6) the chemical's use as a liquid fertilizer for counteracting iron deficiency in plants.

Anticipated residues (OPPTS 860.1540)

A waiver is requested for this data requirement based on this pesticide chemical's (1) low toxicity and risks, as discussed in EPA's BRAD on sodium ferric EDTA and PMRA's proposed and final registration decisions on ferric sodium EDTA (PRD2007-13 and RD2008-04), (2) metabolism of the chemical by mammals, (3) the end-use products' physical state as a dry, solid pellet, (4) the chemical's use as a source of dietary iron for food fortification purposes in the US and approval by the World Health Organization for the same purpose, (4) the chemical's environmental fate, (5) the chemical's use pattern and (6) the chemical's use as a liquid fertilizer for counteracting iron deficiency in plants.

Proposed tolerances (OPPTS 860.1550)

Data submitted in the form of the enclosed petition for an exemption from the requirement of a tolerance. Neudorff is requesting that EPA promulgate a final rule exempting residues of the pesticide chemical sodium ferric EDTA from the requirement of tolerance when used in accordance with good agricultural practice as an active ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. Such a regulation would appear in 40 CFR Part 180.

Reasonable grounds in support of the petition (OPPTS 860.1560)

Data submitted in the form of the enclosed petition for an exemption from the requirement of a tolerance. This petition demonstrates a tolerance exemption for sodium ferric EDTA should be promulgated based on (1) the chemical's low toxicity and risks, as discussed in EPA's BRAD on sodium ferric EDTA and PMRA's proposed and final registration decisions on ferric sodium EDTA (PRD2007-13 and RD2008-04), (2) metabolism of the chemical by mammals, (3) the end-use products' physical state as a dry, solid pellet, (4) the chemical's use as a source of dietary iron for food fortification purposes in the US and approval by the World Health Organization for the same purpose,

(4) the chemical's environmental fate, (5) the chemical's use pattern and (6) the chemical's use as a liquid fertilizer for counteracting iron deficiency in plants.

Submittal of analytical reference standards (OPPTS 860.1650)

A waiver is requested for this data requirement based on this pesticide chemical's (1) low toxicity and risks, as discussed in EPA's BRAD on sodium ferric EDTA and PMRA's proposed and final registration decisions on ferric sodium EDTA (PRD2007-13 and RD2008-04), (2) metabolism of the chemical by mammals, (3) the end-use products' physical state as a dry, solid pellet, (4) the chemical's use as a source of dietary iron for food fortification purposes in the US and approval by the World Health Organization for the same purpose, (4) the chemical's environmental fate, (5) the chemical's use pattern and (6) the chemical's use as a liquid fertilizer for counteracting iron deficiency in plants.

Toxicology – OPPTS Series 870

Acute oral toxicity (OPPTS 870.1100)

Data submitted with application for registration.

Acute dermal toxicity (OPPTS 870.1200)

Data submitted with application for registration.

Acute inhalation toxicity (OPPTS 870.1300)

Data submitted with application for registration.

Acute eye irritation (OPPTS 870.2400)

Data submitted with application for registration.

Acute dermal irritation (OPPTS 870.2500)

Data submitted with application for registration.

Skin sensitization (OPPTS 870.2600)

Data submitted with application for registration.

Hypersensitivity Incidents

No data were found.

90-day oral toxicity (one species) (OPPTS 870.3100

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "[n]o references for feeding studies using Sodium Ferric EDTA were located in the published literature. Rats fed low mineral diets with or without added calcium disodium EDTA for four months had reduced weight gain, but their general condition was comparable to that of controls (Yang, 1964). Rats fed 1%, 5%, or 10% disodium salt of EDTA for 90 days had significantly lower food consumption and weight gain than controls (Wynn et al. 1970). Hematology was comparable among all groups, except that prothrombin time was increased in the 10% group. The only significant necropsy finding was pale livers in the 10% group."

"Mice fed 3750 or 7500 ppm trisodium EDTA for 103 weeks had no treatment-related clinical signs, and gross and microscopic pathology were unremarkable (National Cancer Institute, 1977). A companion study conducted by NCI using rats produced the same results (National Cancer Institute, 1977). In a 12-month feeding study using dogs, Oser et al. (1963) found no significant changes in hematology or urinalysis parameters, and no abnormal gross or microscopic findings in groups receiving up to 250 mg/kg/ body weight/day of calcium disodium EDTA." *Id.* at 8 of 17.

90-day dermal toxicity – rat (OPPTS 870.3250)

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "[t]he end product containing Sodium Ferric EDTA is a pellet that does not produce any dust and is applied directly to the ground. Therefore, it is unlikely that there will be any dermal exposure when the product is applied according to the label directions. Furthermore, Sodium Ferric EDTA was demonstrated to be practically non-toxic (Toxicity Category IV) to rats in an acute dermal toxicity guideline study (MRID 45848104)." *Id.* at 8 of 17.

Apropos of the above determination, the two end-products for which W. Neudorff GmbH KG ("Neudorff") is seeking registrations, i.e., Slugkil 5 and Slugkil 2, and for which Slugkil MP is the manufacturing-use product, are pellets that do not produce any dust and are applied directly to the ground; and, the acute dermal toxicity studies being submitted with this application for registration and the application for registration of Slugkil 5 confirm the practical non-toxicity of the technical grade of the active ingredient.

90-day inhalation toxicity – rat (OPPTS 870.3465)

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "[s]ince the end product is a pellet that does not produce any dust and is applied directly to the ground, it is unlikely that there will be any inhalation exposure when the product is applied according to label directions. Furthermore, Sodium Ferric EDTA was demonstrated to be practically non-toxic (Toxicity Category IV) to rats in an acute inhalation guideline study (MRID 45848105)" *Id.* at 8 and 9 of 17.

Apropos of the above determination, the two end-products for which W. Neudorff GmbH KG ("Neudorff") is seeking registrations, i.e., Slugkil 5 and Slugkil 2, and for which

Slugkil MP is the manufacturing-use product, are pellets that do not produce any dust and are applied directly to the ground; and, the acute inhalation toxicity study being submitted with this application for registration confirms the practical non-toxicity of the technical grade of the active ingredient.

Immunotoxicity (OPPTS 870.3550)

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "[n]o literature was located suggesting that Sodium Ferric EDTA impacts the immune system. FDA has approved calcium disodium EDTA and disodium EDTA as food additives, and these materials are added to a wide range of processed foods at levels of 200 to 500 ppm. Based on the use of EDTA and iron supplements as food ingredients, there do not appear to be any concerns regarding immune system safety issues." *Id.* at 9 of 17.

Prenatal development (OPPTS 870.3700)

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "[t]he teratogenic potential of disodium EDTA has been investigated (Swenerton and Hurley, 1971; Gasset and Akaboshi, 1977; Kimmel, 1977) with variable results. The differences in toxicity shown in the scientific literature probably relate to several factors, such as absorption differences, stress associated with the administration of treatments, different species and strain susceptibility, and interaction with metals (Kimmel, 1977). Since it has been shown that EDTA may chelate zinc (Swenterton and Hurley, 1971), the exchange of iron for zinc is the predominant reaction of concern during pregnancy because of the potential effect of disodium EDTA on zinc balance, and the high sensitivity of the developing embryo to zinc deficiency (Hurley and Swenerton, 1966; Swenerton and Hurley, 1971; Kimmel, 1975; and Kimmel and Slaoan, 1975). Effects of EDTA on zinc balance depend on the EDTA:zinc ratio, and the dietary dose range of 2.5 mg EDTA/kg bw/day recommended by the FAO/WHO Expert Committed on Food Additives (JECFA, 1974) would not be expected to have detrimental effects on zinc balance. Overall, many of the results found in the scientific literature, including Schardein et al. (1981), indicated little or no teratogenic effect of disodium EDTA in rats and rabbits. Based on the submitted data, the active ingredient is not likely to be teratogenic." *Id.* at 9 of 17.

Bacterial reverse mutation test (OPPTS 870.5100)

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "Sodium Ferric EDTA with and without S9 activation was found to be mutagenic in a L5178Y tk+/tk- mouse lymphoma assay, but not mutagenic with or without S9 activation in an Ames *Salmonella* assay (Dunkel et al., 1999). Heimbach et al. (2000) concluded that the positive results seen for sodium ferric EDTA in the mouse lymphoma assay conducted by Dunkel et al. (1999) were most likely due to the sensitivity of L5178Y cells to the abnormally high iron concentrations. No other references suggesting that Ferric iron has mutagenic potential were found in the literature."

"In a L5178Y tk+/tk- mouse lymphoma cell forward mutation assay using trisodium EDTA (McGregor et al., 1988), no mutagenicity was seen with or without added S9. In another study, Heindorff et al. (1983) reported that EDTA inhibits DNA synthesis and repair, and produces a low degree of chromosomal damage and gene mutations in vitro. However, FDA scientists (Lerner et al., 1986) concluded that these events were spurious indicators of genotoxic potential, likely caused by chelation of cations that are important as enzymatic cofactors involved in DNA synthesis in the cell. According to Heindorff et al. (1983) 'the mechanism(s) by which EDTA causes genetic effects is poorly understood. Most data support the idea that EDTA itself does not induce genotoxic effects. Such effects are probably due to the cation deficiency induced by the sequestering agent. Consequently, the ultimate cause of genotoxic effects would consist in variation of the cation level.'" *Id.* at 9 of 17.

<u>In vitro mammalian cell assay (OPPTS 870.5300)</u>

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "Sodium Ferric EDTA with and without S9 activation was found to be mutagenic in a L5178Y tk+/tk- mouse lymphoma assay, but not mutagenic with or without S9 activation in an Ames *Salmonella* assay (Dunkel et al., 1999). Heimbach et al. (2000) concluded that the positive results seen for sodium ferric EDTA in the mouse lymphoma assay conducted by Dunkel et al. (1999) were most likely due to the sensitivity of L5178Y cells to the abnormally high iron concentrations. No other references suggesting that Ferric iron has mutagenic potential were found in the literature."

"In a L5178Y tk+/tk- mouse lymphoma cell forward mutation assay using trisodium EDTA (McGregor et al., 1988), no mutagenicity was seen with or without added S9. In another study, Heindorff et al. (1983) reported that EDTA inhibits DNA synthesis and repair, and produces a low degree of chromosomal damage and gene mutations in vitro. However, FDA scientists (Lerner et al., 1986) concluded that these events were spurious indicators of genotoxic potential, likely caused by chelation of cations that are important as enzymatic cofactors involved in DNA synthesis in the cell. According to Heindorff et al. (1983) 'the mechanism(s) by which EDTA causes genetic effects is poorly understood. Most data support the idea that EDTA itself does not induce genotoxic effects. Such effects are probably due to the cation deficiency induced by the sequestering agent. Consequently, the ultimate cause of genotoxic effects would consist in variation of the cation level.'" *Id.* at 9 of 17.

<u>In vitro mammalian cell assay (OPPTS 870.5375))</u>

Waiver requested for this data requirement. In waiving this data requirement, the BRAD stated "Sodium Ferric EDTA with and without S9 activation was found to be mutagenic in a L5178Y tk+/tk- mouse lymphoma assay, but not mutagenic with or without S9 activation in an Ames *Salmonella* assay (Dunkel et al., 1999). Heimbach et al. (2000) concluded that the positive results seen for sodium ferric EDTA in the mouse lymphoma assay conducted by Dunkel et al. (1999) were most likely due to the sensitivity of

L5178Y cells to the abnormally high iron concentrations. No other references suggesting that Ferric iron has mutagenic potential were found in the literature."

"In a L5178Y tk+/tk- mouse lymphoma cell forward mutation assay using trisodium EDTA (McGregor et al., 1988), no mutagenicity was seen with or without added S9. In another study, Heindorff et al. (1983) reported that EDTA inhibits DNA synthesis and repair, and produces a low degree of chromosomal damage and gene mutations in vitro. However, FDA scientists (Lerner et al., 1986) concluded that these events were spurious indicators of genotoxic potential, likely caused by chelation of cations that are important as enzymatic cofactors involved in DNA synthesis in the cell. According to Heindorff et al. (1983) 'the mechanism(s) by which EDTA causes genetic effects is poorly understood. Most data support the idea that EDTA itself does not induce genotoxic effects. Such effects are probably due to the cation deficiency induced by the sequestering agent. Consequently, the ultimate cause of genotoxic effects would consist in variation of the cation level.'" *Id.* at 9 of 17.

In vivo cytogenetics (OPPTS 870.5385)

Not applicable. The results of Tier I data discussed in the BRAD indicate that this data requirement is not triggered.

In vivo cytogenetics (OPPTS 870.5895)

Not applicable. The results of Tier I data discussed in the BRAD indicate that this data requirement is not triggered.

Dermal outdoor exposure (OPPTS 875.1100)

Not applicable. The product is a manufacturing-use product used to produce end-use pesticide products at indoor facilities. Further, the toxicology data submitted with this application and the BRAD's human health risk assessment indicate that sodium ferric EDTA does not pose a potential hazard to the applicator or user.

Dermal indoor exposure (OPPTS 875.1200)

Not applicable. The toxicology data submitted with this application and the BRAD's human health risk assessment indicate that sodium ferric EDTA does not pose a potential hazard to the applicator or user.

Inhalation outdoor exposure (OPPTS 875.1300)

Not applicable. The product is a manufacturing-use product used to produce end-use pesticide products at indoor facilities. Further, the toxicology data submitted with this application and the BRAD's human health risk assessment indicate that sodium ferric EDTA does not pose a potential hazard to the applicator or user.

Inhalation indoor exposure (OPPTS 875.1400)

Not applicable. The toxicology data submitted with this application and the BRAD's human health risk assessment indicate that sodium ferric EDTA does not pose a potential hazard to the applicator or user.

Biological monitoring (OPPTS 875.1500)

Not applicable. The toxicology data submitted with this application and the BRAD's human health risk assessment indicate that sodium ferric EDTA does not pose a potential hazard to the applicator or user.

Immune response (OPPTS 880.3800)

Not applicable. This Tier III data requirement is not triggered based on the data submitted with this application or the analysis of sodium ferric EDTA in the BRAD.

Reproduction and fertility effects (OPPTS 8703800)

Not applicable. This Tier III data requirement is not triggered based on the data submitted with this application or the analysis of sodium ferric EDTA in the BRAD.

Chronic oral – rodent and nonrodent (OPPTS 870.4100)

Not applicable. This Tier III data requirement is not triggered based on the data submitted with this application or the analysis of sodium ferric EDTA in the BRAD.

Carcinogenicity – two species – rat and mouse (OPPTS 870.4200)

Not applicable. This Tier III data requirement is not triggered based on the data submitted with this application or the analysis of sodium ferric EDTA in the BRAD.

Mammalian spermatogonial chromosome aberration test (OPPTS 870.5380)

Not applicable. This Tier III data requirement is not triggered based on the data submitted with this application or the analysis of sodium ferric EDTA in the BRAD.

Companion animal safety (OPPTS 870.7200)

Not applicable. This Tier III data requirement is not triggered based on the data submitted with this application or the analysis of sodium ferric EDTA in the BRAD.

Product-Specific Data

Product Chemistry – OPPTS Series 880 and 830

Product identity and composition (OPPTS 880.1100)

Data submitted with application for registration.

Description of materials used to produce product (OPPTS 880.1200)

Data submitted with application for registration.

Description of formulation process (OPPTS 880.1200)

Data submitted with application for registration.

Discussion of formation of impurities (OPPTS 880.1400)

Data submitted with application for registration.

Preliminary analysis (OPPTS 830.1700)

Data submitted with application for registration.

Certified limits (OPPTS 830.1750)

Data submitted with application for registration.

Enforcement analytical method (OPPS 830.1800)

Data submitted with application for registration.

Color (OPPTS 830.6302)

This requirement is not applicable to the MP. See 40 CFR § 158.2030.

Physical state (OPPTS 830.6303)

Data submitted with application for registration.

Odor (OPPTS 830.6304)

This requirement is not applicable to the MP. See 40 CFR § 158.2030.

Oxidation/reduction, chemical incompatibility (OPPTS 830.6314)

This requirement is not applicable because the product does not contain an oxidizing or reducing agent. Further, this data requirement is not applicable to products handled by EPA's Biopesticides and Pollution Prevention Division. See 40 CFR § 158.2030.

Flammability (OPPTS 830.6315)

This requirement is not applicable. The product does not contain combustible liquids.

Storage stability (OPPTS 830.6317)

One-month study under accelerated conditions submitted with application for registration. Waiver requested based on this study and the condition that a full one-year study be submitted within one year after the grant of registration.

Miscibility (OPPTS 830.6319)

This requirement is not applicable, because the product is a solid and not an emulsifiable liquid that will be diluted with petroleum solvents.

Corrosion characteristics (OPPTS 830.6320)

One-month study under accelerated conditions submitted with application for registration. Waiver requested based on this study and the condition that a full one-year study be submitted within one year after the grant of registration.

pH (OPPTS 830.7000)

Data submitted with application for registration.

Viscosity (OPPTS 830.7100)

This requirement is not applicable because the product is a solid.

Density/relative density/bulk density (OPPTS 830.7300)

Data submitted with application for registration.

Toxicology – OPPTS Series 870

Acute oral toxicity (OPPTS 870.1100)

Waiver requested for this data requirement. In support of this waiver request, Neudorff is citing and relying on the study developed on the technical grade of the active ingredient ("TGAI") that is being submitted with this application. In this study a single oral dose of 2000 mg/kg b.w. of sodium ferric EDTA to the test animals resulted in no deaths and did not reveal any signs if toxicity. This study places the TGAI in Toxicity Category III for this route of exposure. Because the TGAI contains the active ingredient sodium ferric EDTA at 99.83%, and because Slugkil MP contains the active ingredient at 71.42% and its inert ingredients are on List 4, Slugkil MP is not expected to be in a higher Toxicity Category than the TGAI.

Acute dermal toxicity (OPPTS 870.1200)

Waiver requested for this data requirement. In support of this waiver request, Neudorff is citing and relying on the study developed on the technical grade of the active ingredient ("TGAI") that is being submitted with this application In this study, a single dermal application of 2000 mg/kg b.w. of sodium ferric EDTA to the test animals resulted in no deaths, did not reveal any signs if toxicity, had no influence on animal behavior and no skin reaction was observed. This study places the TGAI in Toxicity Category III for this route of exposure. Because the TGAI contains the active ingredient sodium ferric EDTA at 99.83%, and because Slugkil MP contains the active ingredient at 71.42% and its inert ingredients are on List 4, Slugkil MP is not expected to be in a higher Toxicity Category than the TGAI.

Acute inhalation toxicity (OPPTS 870.1300)

Waiver requested for this data requirement. In support of this waiver request, Neudorff is citing and relying on the study developed on the technical grade of the active ingredient ("TGAI") that is being submitted with this application. This study places the TGAI in Toxicity Category IV for this route of exposure. Because the TGAI contains the active ingredient sodium ferric EDTA at 99.83%, and because Slugkil MP contains the active ingredient at 71.42% and its inert ingredients are on List 4, Slugkil MP is not expected to be in a higher Toxicity Category than the TGAI.

Acute eye irritation (OPPTS 870.2400)

Waiver requested for this data requirement. In support of this waiver request, Neudorff is citing and relying on the study developed on the technical grade of the active ingredient ("TGAI") that is being submitted with this application. This study places the TGAI in Toxicity Category III for this route of exposure. Because the TGAI contains the active ingredient sodium ferric EDTA at 99.83%, and because Slugkil MP contains the active ingredient at 71.42% and its inert ingredients are on List 4, Slugkil MP is not expected to be in a higher Toxicity Category than the TGAI.

Acute dermal irritation (OPPTS 870.2500)

Waiver requested for this data requirement. In support of this waiver request, Neudorff is citing and relying on the study developed on the technical grade of the active ingredient ("TGAI") that is being submitted with this application. This study places the product in Toxicity Category IV for this route of exposure. Because the TGAI contains the active ingredient sodium ferric EDTA at 99.83%, and because Slugkil MP contains the active ingredient at 71.42% and its inert ingredients are on List 4, Slugkil MP is not expected to be in a higher Toxicity Category than the TGAI.

Skin sensitization (OPPTS 870.2600)

Waiver requested for this data requirement. In support of this waiver request, Neudorff is citing and relying on the study developed on the technical grade of the active ingredient ("TGAI") that is being submitted with this application. This study concluded that the TGAI was not a dermal sensitizer. Because the TGAI contains the active ingredient sodium ferric EDTA at 99.83%, and because Slugkil MP contains the active ingredient at 71.42% and its inert ingredients are on List 4, Slugkil MP is not expected to be a dermal sensitizer.

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

September 27, 2010

DELIVERED BY COURIER
Linda Hollis, Chief
Biochemicals Branch
Biopesticides and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S, Crystal Drive
Arlington, VA 22202

Re: Slugkil MP, Slugkil 2 and Slugkil 5
EPA File Symbols 67702-GR, 67702-GE and 67702-GG
Resubmissions in Response to Deficiencies Identified in DERs

Dear Ms. Hollis:

Please find enclosed W. Neudorff GmbH KG's ("Neudorff's") resubmissions on the applications for registration of Slugkil MP (67702-GR), Slugkil 2 (67702-GE) and Slugkil 5 (67702-GG) in response to EPA's Data Evaluation Records "("DERs") on MRIDs 47942501-06, 47941901-03 and 47942001-03. These DERs identify certain deficiencies with respect to Neudorff's applications for registration of the three Slugkil products. In this resubmission, Neudorff addresses the deficiencies by the submission of the enclosed documents and the explanations offered in this letter.

SLUGKIL MP
Deficiency #1 – The name of the active ingredient is inconsistent on the CSF and the product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – There is a discrepancy between the CSFs and MRID 47942501 concerning the suppliers of the active and inert ingredients.
Response – The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
Deficiency #3 – A MSDS or specification sheet must be provided for [redacted].
Response – A MSDS for [redacted] has been inserted in the revised product chemistry (Volume 2) for this product. Three copies of the revised Volume are enclosed.

Inert ingredient information may be entitled to confidential treatment

Deficiency #4 - The methods used to determine color, pH and melting range of sodium ferric EDTA and the results for color, odor and one-year storage stability and corrosion characteristics of Slugkil MP must be provided.
Response – Studies addressing the melting point/melting range, color and odor of the TGAI are enclosed. These studies identify the methods used to determine the data end points. See Volumes 20 and 22. A study identifying the method used to determine the pH of the TGAI is enclosed. See Volume 23. A study addressing the pH, storage stability and corrosion characteristic of Slugkil MP is enclosed. See Volume 21. Three copies of each study are enclosed. Please note that Neudorff is not submitting color and odor data on Slugkil MP because using the MP as a test substance and submitting these data on the MP is not required by 40 CFR § 158.2030.

SLUGKIL 2
Deficiency #1 – The name of the active ingredient is inconsistent on the CSFs and product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – The purity of Slugkil MP must be added to the CSFs for alternate formulations #1, #2, #5, #6, #8, #10 and #12.
Response – These CSFs have been revised to add the purity of Slugkil MP, which is 71.42%. Copies of the revised CSFs are enclosed.
Deficiency #3 – The discrepancies between the CSFs and MRID 47941901 concerning the suppliers of the inert ingredient must be resolved.
Response - The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
Deficiency #4 – A MSDS or specification sheet must be provided for each inert ingredient.
Response – MSDSs for the product's inert ingredients been inserted in the revised product chemistry Volume 2 for this product. Three copies of the revised Volume are enclosed.
Deficiency #5 – The discrepancy between MRID 47941902 and the CSFs concerning the certified limits for the active ingredient must be resolved.
Response – The product's CSFs have been revised to show the same upper and lower certified limits for the active ingredient as shown in the enclosed, revised product chemistry Volume 3. The upper certified limit is based on the upper end of the range of values from the results of the preliminary analysis of five samples of the product, and reflects the variability of the production process, while the lower certified limit reflects the limit allowed by 40 CFR § 158.350.
Deficiency #6 – Oxidation/reduction:chemical incompatibility must be addressed.
Response – This data requirement has been addressed in the enclosed, revised "Correspondence Document: Explanations and Waiver Requests". Because the product does not contain an oxidizing or reducing agent, this data requirement is not applicable. Moreover, this data requirement is not required by 40 CFR § 158.2030.

SLUGKIL 5
Deficiency #1 – The name of the active ingredient is inconsistent on the CSFs and product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – The purity of Slugkil MP must be added to the CSFs for alternate formulations #1, #2, #5, #6, #8, #10 and #12.
Response – These CSFs have been revised to add the purity of Slugkil MP, which is 71.42%. Copies of the revised CSFs are enclosed.

Deficiency #3 – The discrepancies between the CSFs and MRID 47941901 [really 47942001] concerning the suppliers of the inert ingredient must be resolved.
Response - The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
Deficiency #4 – A MSDS or specification sheet must be provided for each inert ingredient.
Response – MSDSs for the product's inert ingredients have been inserted in the revised product chemistry (Volume 2) for this product. Three copies of the revised Volume are enclosed.
Deficiency #5 – The certified limits for the active ingredient must be corrected on the CSFs and in MRID 47941902 [really MRID 47942002].
Response - The product's CSFs have been revised to show the same upper and lower certified limits for the active ingredient as shown in the enclosed, revised product chemistry Volume 3. These certified limits are based on the results of the preliminary analysis of five samples of the product and reflect the variability of the production process.
Deficiency #6 – The mean and relative standard deviation for the repeated analysis to determine precision of the enforcement analytical method must be corrected in MRID 47941902 [really 47942003].
Response – The study director for this study is out of the country until October 5th. However, when he returns, this study will be revised to correct the mean and relative standard deviation. A revised Volume 4 will be submitted shortly after this date.
Deficiency #7 – Oxidation/reduction:chemical incompatibility must be addressed.
Response – This data requirement has been addressed in the enclosed, revised "Correspondence Document: Explanations and Waiver Requests". Because the product does not contain an oxidizing or reducing agent, this data requirement is not applicable. Moreover, this data requirement is not required by 40 CFR § 158.2030.

This resubmission has been discussed with Mr. John Fournier of your staff.

If you have any questions about this submission, please feel free to call me.

Sincerely yours,

Walter G. Talarek
Authorized Agent

Enclosure – Application for Notification

TRANSMITTAL DOCUMENT

1. Name and address of submitter

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

2. Regulatory action in support of which this package is submitted

Resubmission in support of application for registration of Slugkil MP, EPA File Symbol 67702-GR, and in response to Data Evaluation Record on MRIDs 47942501-06

3. Transmittal date

September 27, 2010

4. List of submitted studies

	Volume 1 See MRID 482406	Administrative Materials Letter to Ms. Hollis explaining resubmission EPA Form 8570-1 EPA Forms 8570-4: CSFs for Basic Formulation and Alternate Formulations ##1-4 Labels (5 copies) Correspondence Document: Explanations and Waiver Requests
48240701	Volume 2	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
48240702	Volume 20	Product Chemistry: Melting Point/Melting Point Range, color and odor of TGAI; OPPTS 830.7200
48240703	Volume 21	Product Chemistry: Storage Stability, Corrosion Characteristics and pH of Slugkil MP; OPPTS 830.6317, 830.6320 and 830.7000
48240704	Volume 22	Product Chemistry: Color and Odor of TGAI: OPPTS 830.6302 and 830.6304
48240705	Volume 23	Product Chemistry: Analytical Method for Determination of pH of TGAI; OPPTS 830.7000

Company Official: Walter G. Talarek, Authorized Agent — Signature

Company Name: W. Neudorff GmbH KG

Company Contact: Walter G. Talarek (Name); (703) 759-4837 (Phone)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 1, 2010

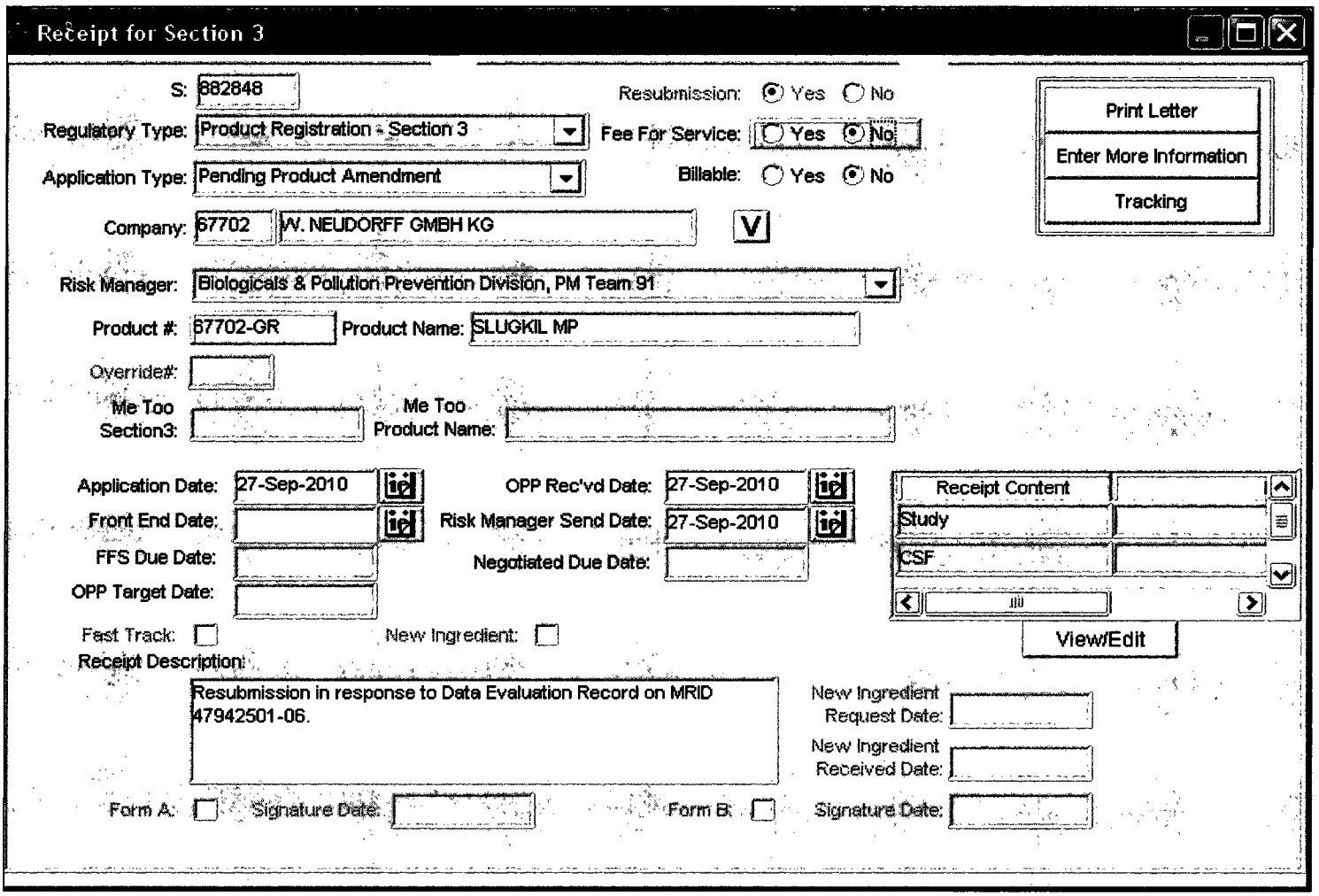
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

W. NEUDORFF GMBH KG
POSTFACH 1209
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 27-SEP-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 882848
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Pending Product Amendment
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 67702 W. NEUDORFF GMBH KG
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GR
Product Name: SLUGKIL MP
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 27-Sep-2010
OPP Rec'vd Date: 27-Sep-2010
Front End Date:
Risk Manager Send Date: 27-Sep-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Resubmission in response to Data Evaluation Record on MRID 47942501-06.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

September 27, 2010

DELIVERED BY COURIER
Linda Hollis, Chief
Biochemicals Branch
Biopesticides and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S, Crystal Drive
Arlington, VA 22202

Re: Slugkil MP, Slugkil 2 and Slugkil 5
EPA File Symbols 67702-GR, 67702-GE and 67702-GG
Resubmissions in Response to Deficiencies Identified in DERs

Dear Ms. Hollis:

Please find enclosed W. Neudorff GmbH KG's ("Neudorff's") resubmissions on the applications for registration of Slugkil MP (67702-GR), Slugkil 2 (67702-GE) and Slugkil 5 (67702-GG) in response to EPA's Data Evaluation Records "("DERs") on MRIDs 47942501-06, 47941901-03 and 47942001-03. These DERs identify certain deficiencies with respect to Neudorff's applications for registration of the three Slugkil products. In this resubmission, Neudorff addresses the deficiencies by the submission of the enclosed documents and the explanations offered in this letter.

SLUGKIL MP
Deficiency #1 – The name of the active ingredient is inconsistent on the CSF and the product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – There is a discrepancy between the CSFs and MRID 47942501 concerning the suppliers of the active and inert ingredients.
Response – The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
Deficiency #3 – A MSDS or specification sheet must be provided for [redacted]
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Deficiency #4 - The methods used to determine color, pH and melting range of sodium ferric EDTA and the results for color, odor and one-year storage stability and corrosion characteristics of Slugkil MP must be provided.
Response – Studies addressing the melting point/melting range, color and odor of the TGAI are enclosed. These studies identify the methods used to determine the data end points. See Volumes 20 and 22. A study identifying the method used to determine the pH of the TGAI is enclosed. See Volume 23. A study addressing the pH, storage stability and corrosion characteristic of Slugkil MP is enclosed. See Volume 21. Three copies of each study are enclosed. Please note that Neudorff is not submitting color and odor data on Slugkil MP because using the MP as a test substance and submitting these data on the MP is not required by 40 CFR § 158.2030.

SLUGKIL 2
Deficiency #1 – The name of the active ingredient is inconsistent on the CSFs and product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
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SLUGKIL 5
Deficiency #1 – The name of the active ingredient is inconsistent on the CSFs and product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – The purity of Slugkil MP must be added to the CSFs for alternate formulations #1, #2, #5, #6, #8, #10 and #12.
Response – These CSFs have been revised to add the purity of Slugkil MP, which is 71.42%. Copies of the revised CSFs are enclosed.

Deficiency #3 – The discrepancies between the CSFs and MRID 47941901 [really 47942001] concerning the suppliers of the inert ingredient must be resolved.
Response - The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
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Deficiency #6 – The mean and relative standard deviation for the repeated analysis to determine precision of the enforcement analytical method must be corrected in MRID 47941902 [really 47942003].
Response – The study director for this study is out of the country until October 5th. However, when he returns, this study will be revised to correct the mean and relative standard deviation. A revised Volume 4 will be submitted shortly after this date.
Deficiency #7 – Oxidation/reduction:chemical incompatibility must be addressed.
Response – This data requirement has been addressed in the enclosed, revised "Correspondence Document: Explanations and Waiver Requests". Because the product does not contain an oxidizing or reducing agent, this data requirement is not applicable. Moreover, this data requirement is not required by 40 CFR § 158.2030.

This resubmission has been discussed with Mr. John Fournier of your staff.

If you have any questions about this submission, please feel free to call me.

Sincerely yours,

Walter G. Talarek
Authorized Agent

Enclosure – Application for Notification

TRANSMITTAL DOCUMENT

1. Name and address of submitter

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

2. Regulatory action in support of which this package is submitted

Resubmission in support of application for registration of Slugkil MP, EPA File Symbol 67702-GR, and in response to Data Evaluation Record on MRIDs 47942501-06

3. Transmittal date

September 27, 2010

4. List of submitted studies

See MRID 482406	Volume 1	Administrative Materials Letter to Ms. Hollis explaining resubmission EPA Form 8570-1 EPA Forms 8570-4: CSFs for Basic Formulation and Alternate Formulations ##1-4 Labels (5 copies) Correspondence Document: Explanations and Waiver Requests
48240701	Volume 2	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
48240702	Volume 20	Product Chemistry: Melting Point/Melting Point Range, color and odor of TGAI; OPPTS 830.7200
48240703	Volume 21	Product Chemistry: Storage Stability, Corrosion Characteristics and pH of Slugkil MP; OPPTS 830.6317, 830.6320 and 830.7000
48240704	Volume 22	Product Chemistry: Color and Odor of TGAI: OPPTS 830.6302 and 830.6304
48240705	Volume 23	Product Chemistry: Analytical Method for Determination of pH of TGAI; OPPTS 830.7000

Company Official: Walter G. Talarek, Authorized Agent — Signature

Company Name: W. Neudorff GmbH KG

Company Contact: Walter G. Talarek (Name); (703) 759-4837 (Phone)

Receipt for Section 3

S: 882848 Resubmission: (•) Yes ( ) No

Regulatory Type: Product Registration - Section 3 Fee For Service: ( ) Yes (•) No

Application Type: Pending Product Amendment Billable: ( ) Yes (•) No

Company: 67702 W. NEUDORFF GMBH KG

Print Letter | Enter More Information | Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 67702-GR Product Name: SLUGKIL MP

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 27-Sep-2010 OPP Rec'vd Date: 27-Sep-2010

Front End Date: 27-Sep-2010 Risk Manager Send Date: 27-Sep-2010

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	
Study	
CSF	

View/Edit

Fast Track: [ ] New Ingredient: [ ]

Receipt Description:

Resubmission in response to Data Evaluation Record on MRID 47942501-06.

New Ingredient Request Date:

New Ingredient Received Date:

Form A: [ ] Signature Date: Form B: [ ] Signature Date:

Recvd 9/27/10 ACB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 28, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WALTER G TALAREK
W. NEUDORFF GMBH KG
POSTFACH 1209
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

PRODUCT NAME: SLUGKIL MP
COMPANY NAME: W. NEUDORFF GMBH KG
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 67702-GR
EPA RECEIPT DATE: 09/27/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-8733.

Sincerely,

P. K. Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {882848V~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 91

Receipt No. S- 882848

EPA File Symbol/Reg. No. 67702-GR

Pin-Punch Date: 9/27/2010

☑ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: $ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Andrew Bycklund Date: 9/28/10

Remarks:

Memorandum

Date: 10 / 06 / 10

To: PM:91, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☑ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Please read instructions on reverse before completing form. Form Approved. No. 2070-0060 Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702-GR	Linda Hollis	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Slugkil MP	91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Resubmission in response to Data Evaluation Record on MRIDs 47942501-06. See the enclosed letter to Ms. Linda Hollis, PM 91, for a full explanation of the resubmission.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Walter G. Talarek	Authorized Agent	
4. Typed Name	**5. Date**	
Walter G. Talarek	September 27, 2010	

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

September 27, 2010

DELIVERED BY COURIER
Linda Hollis, Chief
Biochemicals Branch
Biopesticides and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S, Crystal Drive
Arlington, VA 22202

Re: Slugkil MP, Slugkil 2 and Slugkil 5
EPA File Symbols 67702-GR, 67702-GE and 67702-GG
Resubmissions in Response to Deficiencies Identified in DERs

Dear Ms. Hollis:

Please find enclosed W. Neudorff GmbH KG's ("Neudorff's") resubmissions on the applications for registration of Slugkil MP (67702-GR), Slugkil 2 (67702-GE) and Slugkil 5 (67702-GG) in response to EPA's Data Evaluation Records "("DERs") on MRIDs 47942501-06, 47941901-03 and 47942001-03. These DERs identify certain deficiencies with respect to Neudorff's applications for registration of the three Slugkil products. In this resubmission, Neudorff addresses the deficiencies by the submission of the enclosed documents and the explanations offered in this letter.

SLUGKIL MP
Deficiency #1 – The name of the active ingredient is inconsistent on the CSF and the product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – There is a discrepancy between the CSFs and MRID 47942501 concerning the suppliers of the active and inert ingredients.
Response – The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
Deficiency #3 – A MSDS or specification sheet must be provided for [redacted].
Response – A MSDS for [redacted] has been inserted in the revised product chemistry (Volume 2) for this product. Three copies of the revised Volume are enclosed.

Inert ingredient information may be entitled to confidential treatment

Deficiency #4 - The methods used to determine color, pH and melting range of sodium ferric EDTA and the results for color, odor and one-year storage stability and corrosion characteristics of Slugkil MP must be provided.
Response – Studies addressing the melting point/melting range, color and odor of the TGAI are enclosed. These studies identify the methods used to determine the data end points. See Volumes 20 and 22. A study identifying the method used to determine the pH of the TGAI is enclosed. See Volume 23. A study addressing the pH, storage stability and corrosion characteristic of Slugkil MP is enclosed. See Volume 21. Three copies of each study are enclosed. Please note that Neudorff is not submitting color and odor data on Slugkil MP because using the MP as a test substance and submitting these data on the MP is not required by 40 CFR § 158.2030.

SLUGKIL 2
Deficiency #1 – The name of the active ingredient is inconsistent on the CSFs and product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – The purity of Slugkil MP must be added to the CSFs for alternate formulations #1, #2, #5, #6, #8, #10 and #12.
Response – These CSFs have been revised to add the purity of Slugkil MP, which is 71.42%. Copies of the revised CSFs are enclosed.
Deficiency #3 – The discrepancies between the CSFs and MRID 47941901 concerning the suppliers of the inert ingredient must be resolved.
Response - The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
Deficiency #4 – A MSDS or specification sheet must be provided for each inert ingredient.
Response – MSDSs for the product's inert ingredients been inserted in the revised product chemistry Volume 2 for this product. Three copies of the revised Volume are enclosed.
Deficiency #5 – The discrepancy between MRID 47941902 and the CSFs concerning the certified limits for the active ingredient must be resolved.
Response – The product's CSFs have been revised to show the same upper and lower certified limits for the active ingredient as shown in the enclosed, revised product chemistry Volume 3. The upper certified limit is based on the upper end of the range of values from the results of the preliminary analysis of five samples of the product, and reflects the variability of the production process, while the lower certified limit reflects the limit allowed by 40 CFR § 158.350.
Deficiency #6 – Oxidation/reduction:chemical incompatibility must be addressed.
Response – This data requirement has been addressed in the enclosed, revised "Correspondence Document: Explanations and Waiver Requests". Because the product does not contain an oxidizing or reducing agent, this data requirement is not applicable. Moreover, this data requirement is not required by 40 CFR § 158.2030.

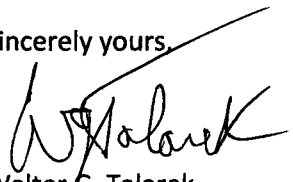
SLUGKIL 5
Deficiency #1 – The name of the active ingredient is inconsistent on the CSFs and product label.
Response – The product's CSFs and label have been revised to name the active ingredient "ferric sodium EDTA". Copies of the revised CSFs and labels are enclosed.
Deficiency #2 – The purity of Slugkil MP must be added to the CSFs for alternate formulations #1, #2, #5, #6, #8, #10 and #12.
Response – These CSFs have been revised to add the purity of Slugkil MP, which is 71.42%. Copies of the revised CSFs are enclosed.

Deficiency #3 – The discrepancies between the CSFs and MRID 47941901 [really 47942001] concerning the suppliers of the inert ingredient must be resolved.
Response - The product's CSF's and product chemistry (Volume 2) have been revised to list the same suppliers for each active and inert ingredient. Copies of the revised CSFs and Volume 2 (three copies) are enclosed.
Deficiency #4 – A MSDS or specification sheet must be provided for each inert ingredient.
Response – MSDSs for the product's inert ingredients have been inserted in the revised product chemistry (Volume 2) for this product. Three copies of the revised Volume are enclosed.
Deficiency #5 – The certified limits for the active ingredient must be corrected on the CSFs and in MRID 47941902 [really MRID 47942002].
Response - The product's CSFs have been revised to show the same upper and lower certified limits for the active ingredient as shown in the enclosed, revised product chemistry Volume 3. These certified limits are based on the results of the preliminary analysis of five samples of the product and reflect the variability of the production process.
Deficiency #6 – The mean and relative standard deviation for the repeated analysis to determine precision of the enforcement analytical method must be corrected in MRID 47941902 [really 47942003].
Response – The study director for this study is out of the country until October 5th. However, when he returns, this study will be revised to correct the mean and relative standard deviation. A revised Volume 4 will be submitted shortly after this date.
Deficiency #7 – Oxidation/reduction:chemical incompatibility must be addressed.
Response – This data requirement has been addressed in the enclosed, revised "Correspondence Document: Explanations and Waiver Requests". Because the product does not contain an oxidizing or reducing agent, this data requirement is not applicable. Moreover, this data requirement is not required by 40 CFR § 158.2030.

This resubmission has been discussed with Mr. John Fournier of your staff.

If you have any questions about this submission, please feel free to call me.

Sincerely yours,



Walter G. Talarek
Authorized Agent

Enclosure – Application for Notification

TRANSMITTAL DOCUMENT

1. Name and address of submitter

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

2. Regulatory action in support of which this package is submitted

Resubmission in support of application for registration of Slugkil MP, EPA File Symbol 67702-GR, and in response to Data Evaluation Record on MRIDs 47942501-06

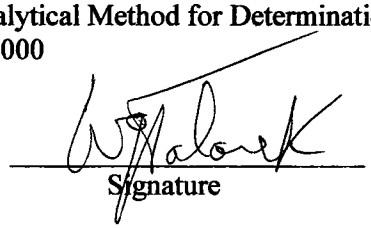
3. Transmittal date

September 27, 2010

4. List of submitted studies

Volume 1	Administrative Materials Letter to Ms. Hollis explaining resubmission EPA Form 8570-1 EPA Forms 8570-4: CSFs for Basic Formulation and Alternate Formulations ##1-4 Labels (5 copies) Correspondence Document: Explanations and Waiver Requests
Volume 2	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
Volume 20	Product Chemistry: Melting Point/Melting Point Range, color and odor of TGAI; OPPTS 830.7200
Volume 21	Product Chemistry: Storage Stability, Corrosion Characteristics and pH of Slugkil MP; OPPTS 830.6317, 830.6320 and 830.7000
Volume 22	Product Chemistry: Color and Odor of TGAI: OPPTS 830.6302 and 830.6304
Volume 23	Product Chemistry: Analytical Method for Determination of pH of TGAI; OPPTS 830.7000

Company Official: Walter G. Talarek
Authorized Agent



Signature

Company Name: W. Neudorff GmbH KG

Company Contact: Walter G. Talarek (703) 759-4837
Name Phone

OAK RIDGE NATIONAL LABORATORY

MANAGED BY UT-BATTELLE FOR THE DEPARTMENT OF ENERGY

June 10, 2010

CUSTODY RECEIPT FOR FIFRA CONFIDENTIAL BUSINESS INFORMATION

TO:	FROM:
Pamela Landis Biopesticides and Pollution Prevention Division Office of Pesticide Programs U.S. Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202	R. H. Ross, Group Leader Toxicology and Hazard Assessment Group 1060 Commerce Park Oak Ridge, Tennessee 37830 (865) 574-7797 FAX (865) 574-5353 email rossrh@ornl.gov

INSTRUCTIONS:

1. Original of this receipt to be signed by recipient and returned to sender.
2. Duplicate of this receipt to be retained by recipient.

TASK No.	MRIDs	Chemical/Agent	WAM	Material Sent	Status	Hours	
						Est. Hours	Actual Hours
10-004	47942501; 47942517-18; 47942507-12	Slugkil MP	Landis	9 DERs 14 Study Reports 1 Custody sheet 1 CD	Draft	48	60
10-005	47941901	Slugkil 2		1 DER 3 Study Reports 1 Custody sheet 1 CD		24	20
10-006	47942001; 47942004-8	Slugkil 5		6 DERs 8 Study Reports 1 Custody sheet 1 CD		48	34

I have personally received from the sender material, enclosures, and attachments as identified above. I assume full responsibility for the safe handling, storage, and transmittal of this material in accordance with existing FIFRA Confidential Business Information regulation

DATE RECEIVED: 6/14/10

SIGNATURE:

OAK RIDGE NATIONAL LABORATORY
MANAGED BY UT-BATTELLE FOR THE DEPARTMENT OF ENERGY

June 10, 2010

CUSTODY RECEIPT FOR FIFRA CONFIDENTIAL BUSINESS INFORMATION

TO: Pamela Landis Biopesticides and Pollution Prevention Division Office of Pesticide Programs U.S. Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202	FROM: R. H. Ross, Group Leader Toxicology and Hazard Assessment Group 1060 Commerce Park Oak Ridge, Tennessee 37830 (865) 574-7797 FAX (865) 574-5353 email rossrh@ornl.gov

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10-006	47942001; 47942004-8	Slugkil 5		6 DERs 8 Study Reports 1 Custody sheet 1 CD		48	34

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DATE RECEIVED: 6/14/10

SIGNATURE:

OAK RIDGE NATIONAL LABORATORY

MANAGED BY UT-BATTELLE FOR THE DEPARTMENT OF ENERGY

June 10, 2010

CUSTODY RECEIPT FOR FIFRA CONFIDENTIAL BUSINESS INFORMATION

TO: Pamela Landis Biopesticides and Pollution Prevention Division Office of Pesticide Programs U.S. Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202	FROM: R. H. Ross, Group Leader Toxicology and Hazard Assessment Group 1060 Commerce Park Oak Ridge, Tennessee 37830 (865) 574-7797 FAX (865) 574-5353 email rossrh@ornl.gov

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TASK No.	MRIDs	Chemical/Agent	WAM	Material Sent	Status	Hours	
						Est. Hours	Actual Hours
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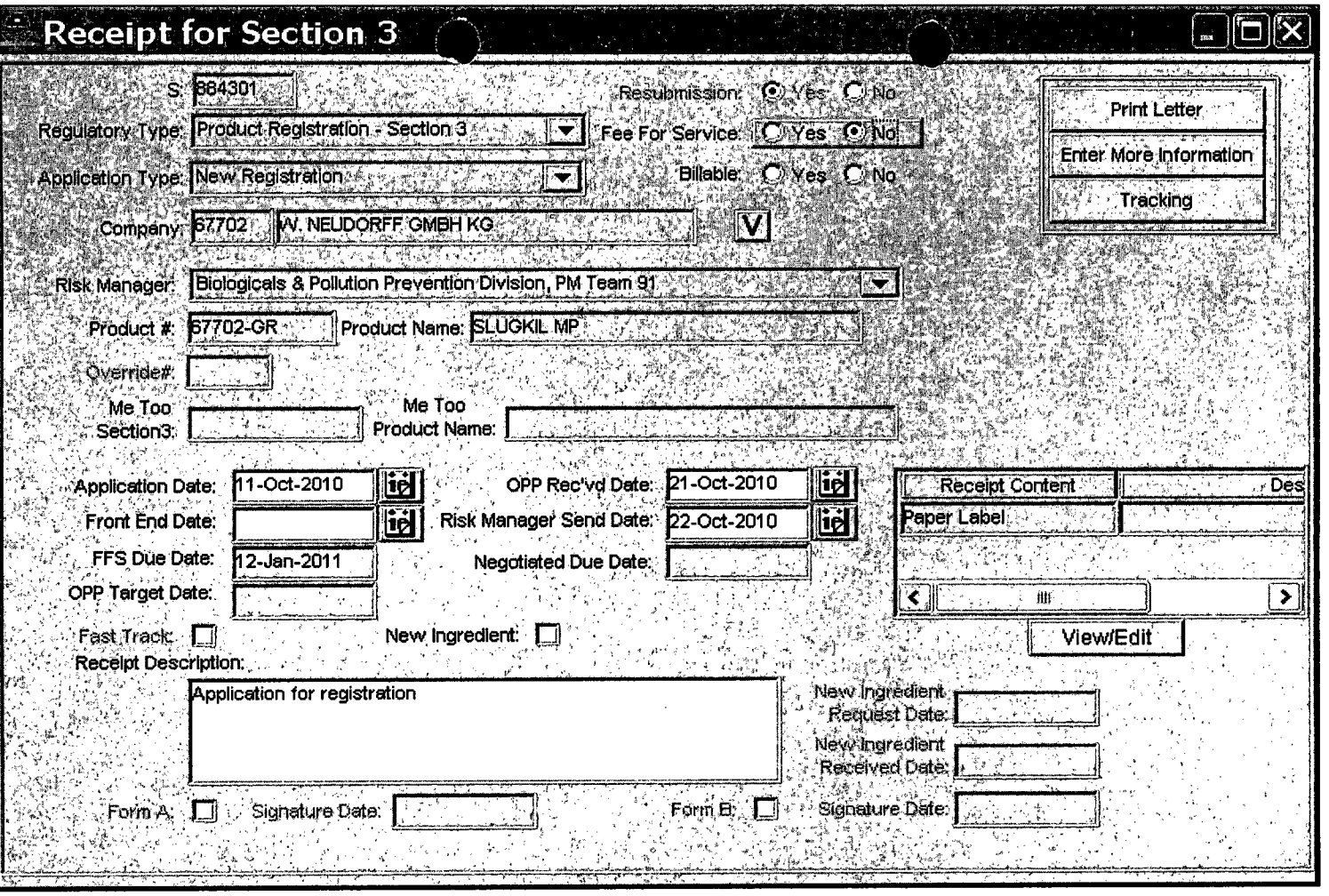
10-005	47941901	Slugkil 2		1 DER 3 Study Reports 1 Custody sheet 1 CD		24	20
10-006	47942001; 47942004-8	Slugkil 5		6 DERs 8 Study Reports 1 Custody sheet 1 CD		48	34

I have personally received from the sender material, enclosures, and attachments as identified above. I assume full responsibility for the safe handling, storage, and transmittal of this material in accordance with existing FIFRA Confidential Business Information regulation

DATE RECEIVED: 6/14/10

SIGNATURE:


Receipt for Section 3
S: 864301
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 67702 W. NEUDORFF GMBH KG
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GR
Product Name: SLUGKIL MP
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 11-Oct-2010
OPP Rec'vd Date: 21-Oct-2010
Front End Date:
Risk Manager Send Date: 22-Oct-2010
FFS Due Date: 12-Jan-2011
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Paper Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Application for registration
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

October 11, 2010

DELIVERED BY COURIER
Linda Hollis, PM 91
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
c/o Document Processing Desk
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Applications for Registration
Slugkil MP; Slugkil 5; and Slugkil 2
EPA File Symbols 67702-GR, 67702-GE, and 67702-GG

Dear Ms. Hollis:

On behalf of W. Neudorff GmbH KG ("Neudorff"), I am submitting revised labels in support of Neudorff's pending applications for registration of Slugkil MP, EPA File Symbol 67702-GR, Slugkil 2, EPA file Symbol 67702-GE, and Slugkil 5, EPA File Symbol,67702-GG. In essence, the labels for these three products have been revised to include the following optional claim: "The active ingredient in this product is exempt from the requirement for a tolerance when used as a molluscicide in or on all food commodities".

In addition, the alternate brand name "Ferrox" is being added to the application for registrtiom for Slugkil 5. The addition of the alternate brand name is indicated in brackets on pages 1, 2 and 9 of the product's revised label.

Five (5) copies of each product's label are enclosed.

If you have any questions about these applications for registration, please feel free to call me.

Sincerely yours,

Walter G. Talarek
Authorized Agent

Enclosures: EPA Forms 8570-1 (3)
Labels

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060 Print Form

EPA United States Environmental Protection Agency Washington, DC 20460

[ ] Registration [ ] Amendment [X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 67702-GR
2. EPA Product Manager: Linda Hollis
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): Slugkil MP
PM#: 91
5. Name and Address of Applicant *(Include ZIP Code)*:
W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620
[ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised label in support of application for registration. See the enclosed letter to Ms. Linda Hollis, PM 91, for an explanation of the revised label. Five (5) copies of the revised label are attached.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) Retail Container
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Walter G. Talarek	Authorized Agent
4. Typed Name: Walter G. Talarek	5. Date: October 11, 2010

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

DATA EVALUATION RECORD

SLUGKIL MP (FENAEDTA)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (870.1100)
MRID 47942507

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 10-004

Primary Reviewer:
Susan Chang, M.S.

Signature: Susan Chang
Date: JUN 10 2010

Secondary Reviewers:
H. Tim Borges, Ph.D., M.T.(A.S.C.P.), D.A.B.T.

Signature: Tim Borges
Date: JUN 10 2010

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: JUN 10 2010

Quality Assurance:
Eric Lewis, M.S.

Signature: Eric B. Lewis
Date: JUN 10 2010

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Oral Toxicity - Rats (OPPTS 870.1100)
MRID NO:	47942507
DP BARCODE NO:	DP 373965
DECISION NO:	425379
SUBMISSION NO:	866101
TEST MATERIAL:	FeNaEDTA (EPA Reg. No. 67702-GR, ethylenediaminetetraacetic acid iron (III) sodium salt, containing 69.9% EDTA, a.i.)
PROJECT NO:	21617 (Report No.)
SPONSOR:	Neudorff GmbH KG, Postfach 1209, An der Mühle 3, D-31860 Emmerthal, Germany
TESTING FACILITY:	LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, P.O. Box 920461, D-21134 Hamburg, Germany
TITLE OF REPORT:	Acute Oral Toxicity
AUTHOR:	Dr. Phil. J. Leuschner
STUDY COMPLETED:	September 17, 2007
GOOD LABORATORY PRACTICE:	GLP Compliant, according to EC method B.1 tris (2004/73/EC) and OECD guideline 423 (ATC method)
CONCLUSION:	The oral LD_{50} for female rats was greater than 2000 mg/kg.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. **Test Material**: FeNaEDTA - ethylenediaminetetraacetic acid iron (III) sodium salt, Batch No. 080 507, containing 69.9% EDTA, a.i.

2. **Test Animals:** Six female CD/Crl:CD(SD) rats were received from Charles River Laboratories, Research Models and Services, Germany GmbH, Sandhofer Weg 7, 97633 Sulzfeld, Germany and weighed 177-183 g on the day of dosing. The young adult animals, 7 weeks old, were housed in groups of three animals in Makrolon cages (type III). The animals were fed commercial diet, ssniff® R/M-H V1534 (ssniff Spezialdiäten GmbH, 59494 Soest, Germany). Drinking water in bottles was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 22±3°C; relative humidity, 55±15%; and photoperiod, 12 hour light/dark cycle. The air changes per hour were not reported.

3. **Methods:** Rats were identified by colored marks and cage label: Nos. 1f to 6f and were acclimated for at least 5 days and fasted approximately 16 hours prior to dosing. The test material (2000 mg/kg body weight, suspended in 0.8% aqueous hydroxypropylmethyl-cellulose gel) was dosed by gavage (Table 1). Body weight was recorded prior to dosing, and on test days 8 and 15. The test animals were observed for clinical signs of toxicity before and immediately after treatment, at 5, 15, 30, and 60 minutes, and 3, 6, and 24 hours post-dosing and at least daily for 14 days. Mortality was checked at least once daily. All animals were necropsied at the end of the study.

II. RESULTS:

1. **Mortality:** All rats survived the study.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg)	Males	Females	Combined
2000	-	0/3	-
2000	-	0/3	-

Data taken from Table 1, p. 21, MRID 47942507.

2. **Body Weight:** All rats gained weight during the study.

3. **Clinical Observations:** No signs of toxicity were revealed.

4. **Gross Necropsy:** No pathological findings were noted at necropsy.

III. DISCUSSION:

The oral LD_{50} for female rats was greater than 2000 mg/kg. This places FeNaEDTA in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

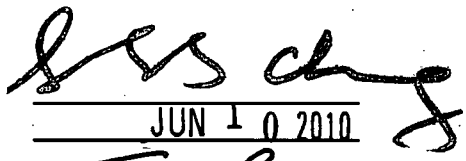
SLUGKIL MP (FENAEDTA)

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (870.1200)
MRID 47942508

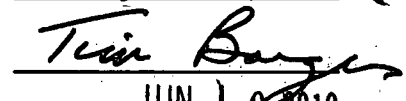
Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 10-004

Primary Reviewer:
Susan Chang, M.S.

Signature: 
Date: JUN 10 2010

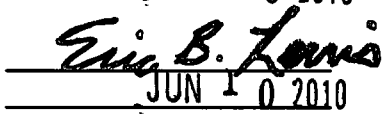
Secondary Reviewers:
H. Tim Borges, Ph.D., M.T.(A.S.C.P.), D.A.B.T.

Signature: 
Date: JUN 10 2010

Robert H. Ross, M.S., Group Leader

Signature: 
Date: JUN 10 2010

Quality Assurance:
Eric Lewis, M.S.

Signature: 
Date: JUN 10 2010

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Dermal Toxicity - Rats (OPPTS 870.1200)
MRID NO:	47942508
DP BARCODE NO:	DP 373965
DECISION NO:	425379
SUBMISSION NO:	866101
TEST MATERIAL:	FeNaEDTA (EPA Reg. No. 67702-GR, ethylenediaminetetraacetic acid iron (III) sodium salt, containing 69.9% EDTA, a.i.)
PROJECT NO:	21618 (Report No.)
SPONSOR:	Neudorff GmbH KG, Postfach 1209, An der Mühle 3, D-31860 Emmerthal, Germany
TESTING FACILITY:	LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, P.O. Box 920461, D-21134 Hamburg, Germany
TITLE OF REPORT:	Acute Dermal Toxicity Study
AUTHOR:	Dr. Phil. J. Leuschner
STUDY COMPLETED:	September 17, 2007
GOOD LABORATORY PRACTICE:	GLP Compliant, according to EC method B.3 (92/69/EEC) and OECD guideline 402
CONCLUSION:	The dermal LD_{50} for males, females, and combined sexes was greater than 2000 mg/kg.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. **Test Material:** FeNaEDTA - ethylenediaminetetraacetic acid iron (III) sodium salt, Batch No. 080 507, containing 69.9% EDTA, a.i.

2. **Test Animals:** Five male and five female CD/Crl:CD(SD) rats were received from Charles River Laboratories, Research Models and Services, Germany GmbH, Sandhofer Weg 7, 97633 Sulzfeld, Germany and weighed 222-253 g (males) and 207-230 g (females) on the day of treatment. The young adult animals, 51-65 days old, were housed individually in Makrolon cages (type III). The animals were fed commercial diet, ssniff® R/M-H V1534 (ssniff Spezialdiäten GmbH, 59494 Soest, Germany). Drinking water in bottles was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 22±3°C; relative humidity, 55±15%; and photoperiod, 12 hour light/dark cycle. The air changes per hour were not reported.

3. **Methods:** Rats were identified by colored marks and cage label: Male – Nos. 1m to 5m; Female – Nos. 6f to 10f. The rats were acclimated for at least 5 days. The test material (2000 mg/kg body weight), suspended in water, was applied to 8 layers of gauze and placed over a 5 cm x 6 cm area (approximately 10% of body surface) of the shaved dorsal trunk. The gauze was covered with plastic sheet and secured with adhesive plaster. The coverings were removed after 24 hours. Body weight was recorded prior to dosing, and on test days 8 and 15. The test animals were observed for clinical signs of toxicity before and immediately after treatment, at 5, 15, 30, and 60 minutes, and at 3, 6, and 24 hours post-treatment, and at least daily for 14 days. The skin was observed for erythema, edema, and necrosis daily. Mortality was checked at least once daily. All animals were necropsied at the end of the study.

II. RESULTS:

1. **Mortality:** All rats survived the study.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg)	Males	Females	Combined
2000	0/5	0/5	0/10

Data taken from Table 1, p. 22, MRID 47942508.

2. **Clinical Observations:** No skin reactions or clinical signs of toxicity were noted throughout the study.

3. **Body Weight:** All rats gained weight during the study.

4. **Gross Necropsy:** No pathological findings were noted at necropsy.

III. DISCUSSION:

The acute dermal LD_{50} for males, females, and combined sexes was greater than 2000 mg/kg. This places FeNaEDTA in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

SLUGKIL MP (FENAEDTA)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (870.2400)
MRID 47942509

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 10-004

Primary Reviewer:
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Signature: 
Date: JUN 10 2010

Secondary Reviewers:
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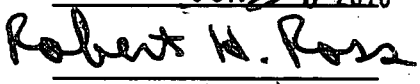
Date: JUN 10 2010

Robert H. Ross, M.S., Group Leader

Signature: 
Date: JUN 10 2010

Quality Assurance:
Eric Lewis, M.S.

Signature: 
Date: JUN 10 2010

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Eye Irritation - Rabbits (OPPTS 870.2400)
MRID NO:	47942509
DP BARCODE NO:	DP 373965
DECISION NO:	425379
SUBMISSION NO:	866101
TEST MATERIAL:	FeNaEDTA (EPA Reg. No. 67702-GR, ethylenediaminetetraacetic acid iron (III) sodium salt, containing 69.9% EDTA, a.i.)
PROJECT NO:	21621 (Report No.)
SPONSOR:	Neudorff GmbH KG, Postfach 1209, An der Mühle 3, D-31860 Emmerthal, Germany
TESTING FACILITY:	LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, P.O. Box 920461, D-21134 Hamburg, Germany
TITLE OF REPORT:	Primary Eye Irritation
AUTHOR:	Dr. J. Leuschner
STUDY COMPLETED:	August 7, 2007
GOOD LABORATORY PRACTICE:	GLP Compliant, according to EC method B.5. (2004/73/EC) and OECD guideline 405
CONCLUSION:	Corneal opacity was noted on 1/3 rabbits at 24 hours after test material instillation with resolution by day 7. Iritis was not noted on any rabbit during the study. No positive conjunctival irritation was noted on any rabbit. Some hyperemic blood vessels were noted on animal No. 1 at 60 minutes after test material instillation, on animal No. 2 at 60 minutes through 48 hours, and on animal No. 3 at 24 hours through day 4. The maximum average score was 3.0 at 24, 48, and 72 hours after test material instillation under the assumption that the area of opacity was 1/4 and discharge scores were 0. FeNaEDTA was mildly irritating.
CLASSIFICATION:	ACCEPTABLE – TOXICITY CATEGORY III

I. STUDY DESIGN:

1. **Test Material:** FeNaEDTA - ethylenediaminetetraacetic acid iron (III) sodium salt, Batch No. 080 507, containing 69.9% EDTA, a.i.

2. **Test Animals:** Three male young adult Himalayan rabbits were received from LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Branch Löhndorf, 24601 Löhndorf/Post Wankendorf, Germany. The animals were housed individually in cages. The animals were fed commercial diet, ssniff® K-H V2333 (ssniff Spezialdiäten GmbH, 59494 Soest, Germany). Tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 20±3°C; relative humidity, 30-70%; air changes, 60 per hour; and photoperiod, 12 hour light/dark cycle.

3. **Methods:** Rabbits were tattooed (Nos. 1, 2, and 3) and acclimated for at least 20 days. The test material (100 mg/eye/animal) was applied into the conjunctival sac of the right eye, and the eye held closed for approximately one second. The left eye served as control. One hour after treatment the eye was rinsed with 20 mL sodium chloride solution. The eyes were examined and scored 1, 24, 48 and 72 hours and at 4 and 7 days after test material instillation.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.

2. **Ocular Lesions:** Corneal opacity was noted on 1/3 rabbits at 24 hours after test material instillation with resolution by day 7 (Table 1). Iritis was not noted on any rabbit during the study (Table 2). No positive conjunctival irritation (score ≥ 2) was noted on any rabbit. Some hyperemic blood vessels were noted on animal No. 1 at 60 minutes after test material instillation, on animal No. 2 at 60 minutes through 48 hours, and on animal No. 3 at 24 hours through day 4. The maximum average score was 3.0 at 24, 48, and 72 hours after test material instillation under the assumption that the area of opacity was 1/4 and discharge scores were 0 (Table 3).

TABLE 1. Individual Male (M) and Female (F) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)

Animal No.	1 hour		24 hours		48 hours		72 hours		4 days		5 days		6 days		7 days	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
1	0	-[a]	0	-	0	-	0	-	0	-	0	-	0	-	0	-
2	0	-	0	-	0	-	0	-	0	-	0	-	0	-	0	-
3	1	-	1	-	1	-	1	-	1	-	1	-	1	-	0	-

Irritation score is based on Draize Method

[a] Area of opacity not reported; at 24 hours fluorescein test: animal No. 3, corneal staining up to ¼ the surface.

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris								
Score Conditions	**1 hour**	**24 hours**	**48 hours**	**72 hours**	**4 days**	**5 days**	**6 days**	**7 days**
Conjunctiva								
Erythema	0 to 1	0 to 1	0 to 1	0 to 1	0 to 1	0	0	0
Chemosis	0	0	0	0	0	0	0	0
Discharge	-[a]	-	-	-	-	-	-	-
Iris	0	0	0	0	0	0	0	0

Irritation score is based on Draize Method

[a] Not reported

Scale for Scoring Ocular Lesions

Cornea

A. Opacity-degree of density (area most dense taken for reading)

No ulceration or opacity 0
Scattered or diffuse areas of opacity (other than slight dulling of normal luster), details of iris clearly visible 1
Easily discernible translucent areas, details of iris slightly obscured 2
Nacreous areas, no details of iris visible, size of pupil barely discernible 3
Opaque cornea, iris not discernible through the opacity 4

Iris

A. Values

Normal 0
Marked deepened rugae; congestion; swelling; moderate circumcorneal hyperemia, or injection; iris reactive to light (a sluggish reaction is considered to be an effect) 1
No reaction to light, hemorrhage, gross destruction (any or all of these) 2

Conjunctivae

A. Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)

Normal 0
Some blood vessels hyperemic (injected) 1
Diffuse, crimson color; individual vessels not easily discernible 2
Diffuse beefy red 3

B. Chemosis

Normal 0
Some swelling above normal 1
Obvious swelling with partial eversion of lids 2
Swelling with lids about half closed 3
Swelling with lids more than half closed 4

TABLE 3. Summary of Total[a] and Primary Eye Irritation Scores with Time								
Animal #	1 h	24 h	48 h	72 h	4 d	5 d	6 d	7 d
1	2	0	0	0	0	0	0	0
2	0	2	2	2	0	0	0	0
3	0	7	7	7	7	5	5	0
Average scores[b]	0.7	3.0	3.0	3.0	2.3	1.7	1.7	0.0

[a]Formula: Total Irritation Score = I + II + III, where,
I = Corneal Score = [Density (A) x Area (B)] x 5
II = Iris Score = Severity x 5
III = Conjunctival Score = [Erythema (A) + Chemosis (B) + Discharge (C)] x 2
Under the assumption that the area of opacity was 1/4 and discharge scores were 0.
[b]Average Primary Irritation = Sum of Total Irritation Scores ÷ 3

III. DISCUSSION:

Corneal opacity was noted on 1/3 rabbits at 24 hours after test material instillation with resolution by day 7. Iritis was not noted on any rabbit during the study. No positive conjunctival irritation (score ≥ 2) was noted on any rabbit. Some hyperemic blood vessels were noted on animal No. 1 at 60 minutes after test material instillation, on animal No. 2 at 60 minutes through 48 hours, and on animal No. 3 at 24 hours through day 4. The maximum average score was 3.0 at 24, 48, and 72 hours after test material instillation under the assumption that the area of opacity was 1/4 and discharge scores were 0. FeNaEDTA was mildly irritating and is in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

SLUGKIL MP (FENAEDTA)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (870.2500)
MRID 47942510

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
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Prepared by
Toxicology and Hazard Assessment Group
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Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 10-004

Primary Reviewer:
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Signature:
Date: JUN 10 2010

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Signature:
Date: JUN 10 2010

Robert H. Ross, M.S., Group Leader

Signature:
Date: JUN 10 2010

Quality Assurance:
Eric Lewis, M.S.

Signature:
Date: JUN 10 2010

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Primary Dermal Irritation - Rabbits (OPPTS 870.2500)
MRID NO:	47942510
DP BARCODE NO:	DP 373965
DECISION NO:	425379
SUBMISSION NO:	866101
TEST MATERIAL:	FeNaEDTA (EPA Reg. No. 67702-GR, ethylenediaminetetraacetic acid iron (III) sodium salt, containing 69.9% EDTA, a.i.)
PROJECT NO:	21620 (Report No.)
SPONSOR:	Neudorff GmbH KG, Postfach 1209, An der Mühle 3, D-31860 Emmerthal, Germany
TESTING FACILITY:	LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, P.O. Box 920461, D-21134 Hamburg, Germany
TITLE OF REPORT:	Primary Dermal Irritation
AUTHOR:	Dr. J. Leuschner
STUDY COMPLETED:	August 7, 2007
GOOD LABORATORY PRACTICE:	GLP Compliant, according to EC method B.4. (2004/73/EC) and OECD guideline 404
CONCLUSION:	Very slight erythema was noted on 1/3 rabbits 60 minutes after patch removal with clearance by 24 hours. The primary irritation index was 0.1. FeNaEDTA was essentially non-irritating.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test Material:** FeNaEDTA - ethylenediaminetetraacetic acid iron (III) sodium salt, Batch No. 080 507, containing 69.9% EDTA, a.i.

2. **Test Animals:** Three male young adult Himalayan rabbits were received from LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Branch Löhndorf, 24601 Löhndorf/Post Wankendorf, Germany. The animals were housed individually in cages. The animals were fed commercial diet, ssniff® K-H V 2333 (ssniff Spezialdiäten GmbH, 59494 Soest, Germany). Tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 20±3°C; relative humidity, 30-70%; air changes, 60 per hour; and photoperiod, 12 hour light/dark cycle.

3. **Methods:** Rabbits were tattooed (Nos. 1, 2, and 3) and acclimated for at least 20 days. The fur on the dorsal trunk of each rabbit was clipped on the day prior to treatment. One thousand mg of the test material were mixed with 0.5 mL water. The rabbits were treated with 500 mg of test material (= 750 mg of the test mixture) applied to an approximately 6 cm^2 clipped intact dose site, and the site covered with gauze patch. The patch was secured with non-irritating tape. The covering was removed 4 hours later. Dermal examination was recorded at 60 minutes, and 24, 48, and 72 hours after removal of the patch.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.

2. **Dermal responses:** Very slight erythema was noted on 1/3 rabbits 60 minutes after patch removal with clearance by 24 hours. The primary irritation index was 0.1.

Irritation Scores:

TABLE 1. Summary of individual rabbit's dermal irritation scores with time

	Hours			
Animal Nos.	1	24	48	72
1	1/0[a]	0/0	0/0	0/0
2	0/0	0/0	0/0	0/0
3	0/0	0/0	0/0	0/0

Data taken from p. 27, MRID 47942510.
[a]Erythema/Edema

Description of rating method:

Evaluation of Skin Reaction:	**Score**
Erythema formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation preventing erythema reading	4

Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised by more than 1 mm extending beyond the area of exposure)	4

III. DISCUSSION:

Very slight erythema was noted on 1/3 rabbits 60 minutes after patch removal with clearance by 24 hours. The primary irritation index was 0.1. FeNaEDTA was essentially non-irritating and is in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

SLUGKIL MP (FENAEDTA)

STUDY TYPE: SKIN SENSITIZATION (LOCAL LYMPH NODE ASSAY) - MICE (870.2600)
MRID 47942511

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 10-004

Primary Reviewer:
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Signature: 
Date: JUN 10 2010

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Signature: 
Date: JUN 10 2010

Robert H. Ross, M.S., Group Leader

Signature: 
Date: JUN 10 2010

Quality Assurance:
Eric Lewis, M.S.

Signature: 
Date: JUN 10 2010

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Skin Sensitization (local lymph node assay) - mice (OPPTS 870.2600)
MRID NO:	47942511
DP BARCODE NO:	DP 373965
DECISION NO:	425379
SUBMISSION NO:	866101
TEST MATERIAL:	FeNaEDTA (EPA Reg. No. 67702-GR, ethylenediaminetetraacetic acid iron (III) sodium salt, containing 69.9% EDTA, a.i.)
PROJECT NO:	21622 (Report No.)
SPONSOR:	Neudorff GmbH KG, Postfach 1209, An der Mühle 3, D-31860 Emmerthal, Germany
TESTING FACILITY:	LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, P.O. Box 920461, D-21134 Hamburg, Germany
TITLE OF REPORT:	Skin Sensitization
AUTHOR:	Dr. J. Haferkorn
STUDY COMPLETED:	September 27, 2007
GOOD LABORATORY PRACTICE:	GLP Compliant, according to EC method B.42 (2004/73/EC) and OECD guideline 429
CONCLUSION:	No statistically significant increases in lymph node cell counts or ear weights were found in treated mice. The slight increase of the lymph node weight in the test material treated groups was regarded as spontaneous. The positive control produced a dermal sensitization response in mice. FeNaEDTA was not a dermal sensitizer.
CLASSIFICATION:	ACCEPTABLE based on concurrence with OECD TG 429; however, the local lymph node assay procedure "was never validated for mixtures by the assay creators. It is undergoing a validation step through ICCVAM - which is a lead NIEHS group of all gov't agency."

I. STUDY DESIGN:

1. **Test material:** FeNaEDTA - ethylenediaminetetraacetic acid iron (III) sodium salt, Batch No. 080 507, containing 69.9% EDTA, a.i.

2. **Test animals:** Forty-six female CBA/JNCrj mice received from Charles River Laboratories, Research Models and Services, Germany GmbH, Sandhofer Weg 7, 97633 Sulzfeld, Germany were assigned to groups and weighed 20-24 g at experiment start. The young adult animals, approximately 8-10 weeks old, were housed individually in Makrolon cages (type III). The animals were fed commercial diet, ssniff® R/M-H V 1543 (ssniff Spezialdiäten GmbH, 59494 Soest, Germany). Tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 22±3°C; relative humidity, 55±15%; air changes, 10 per hour; and photoperiod, 12 hour light/dark cycle.

3. **Methods:** The mice were identified by cage label and grouped: Group 1 [vehicle control; acetone:olive oil (3 + 1, v/v)] – Nos. 1 to 6; Group 2 (10% w/w test material in vehicle) – Nos. 7 to 12; Group 3 (25% w/w test material in vehicle) – Nos. 13 to 18; Group 4 (50% w/w test material in vehicle) – Nos. 19 to 24; Group 6 [positive control; 30% v/v α-hexylcinnamic aldehyde in vehicle) – Nos. P1 to P6. The mice were acclimated for at least five days. The dermal sensitization potential of the test material was examined using the local lymph node assay (LLNA). A preliminary dose-range-finding study was conducted in two animals per dose level (0, 0.5, 1, 2.5, 5, 10, 25, and 50% test material in acetone/olive oil (3+1 v/v)). No sensitizing potential was observed. Hence, the main study concentrations of 10, 25, and 50% w/w test material in acetone/olive oil (3+1 v/v) were used. Body weight was recorded on test day 1 and prior to sacrifice on test day 4. Clinical observations were performed prior to each dose and once daily, and the mice were checked frequently throughout the day. Twenty-five µL of the test material were administered topically to the dorsum of each mouse ear for 3 consecutive days (test days 1 to 3) at 0 [vehicle control: acetone:olive oil (3 + 1, v/v)], 10, 25, and 50% test material in vehicle control; and 30% v/v α-hexylcinnamic aldehyde in vehicle as positive control; respectively. Twenty-four hours after the last application (test day 4), the mice were sacrificed. Ear swelling measurements were carried out at the helical edge of both ears using an Oditest micrometer. Punch biopsies of 8 mm in diameter of the apical area of both ears were prepared and immediately weighed. Lateral pairs of auricular lymph nodes draining the ear tissue were excised, carefully separated from remaining fatty tissue, and weighed immediately following preparation. The lymph nodes were then stored on ice in PBS/0.5% BSA and single cell suspensions prepared by mechanical tissue disaggregation. The cells were counted automatically in a cell counter.

II. RESULTS:

1. **Mortality:** All animals survived the study.

2. **Body Weight:** One mouse in the 50% w/w test material group slightly lost weight. One mouse in the 10% w/w test material group, two mice in the 25% w/w test material group, three mice in the 50% w/w test material group, and five mice in the positive control group did not gain weight.

3. **Clinical signs of Toxicity:** No clinical signs of toxicity were noted in the study.

4. **Stimulation Index Data:** There were no statistically significant increases for the lymph node cell counts and ear weights for the test material treated groups (Table 1). The slight increase

of the lymph node weight in the test material treated groups was regarded as spontaneous, as no statistical significance was noted and the weights obtained were within the normal range observed for control animals. The stimulation indices were calculated by dividing the average lymph node cell counts or ear weights per group of the test material treated animals by the vehicle treated ones. The stimulation indices for the lymph node cell counts were 1.098, 1.170, and 1.045 for 10%, 25%, and 50% test material, respectively. The stimulation indices for the ear weights were 1.037, 1.043, and 1.049 for 10%, 25%, and 50% test material, respectively. The stimulation indices for lymph node cell count, lymph node weight, and ear weight were 1.461, 1.517, and 1.238, respectively, for the positive control. Threshold values of the stimulation indices of lymph node cell count and ear weight were calculated by dividing the average values per group of the test material treated animals by the vehicle treated ones. The stimulation indices for the cell counts above 1.4 or ear weight above 1.1 are considered positive. The positive control produced a dermal sensitization response in mice. FeNaEDTA did not produce a dermal sensitization response in mice and was not a dermal sensitizer.

Table 1 Stimulation Indices[a]

Group	Material tested	No. of animals	Lymph node cell count	Lymph node weight	Ear weight	Difference of ear thickness
1	Vehicle control	6	1.000	1.000	1.000	1.000
2	10% FeNaEDTA	6	1.098	1.034	1.037	1.070
3	25% FeNaEDTA	6	1.170	1.138	1.043	1.113
4	50% FeNaEDTA	6	1.045	1.172	1.049	1.116
6	Positive Control	6	1.461*	1.517*	1.238	1.135

[a] Data taken from p. 21, MRID 47942511.

* Lymph node cell count and lymph node weight significant different from negative control (at $p \leq 0.01$)

III. DISCUSSION:

No statistically significant increases in the indices for the lymph node cell count and ear weight for the test material treated groups were found. The slight increase of the lymph node weight in the test material treated groups was regarded as spontaneous, as no statistical significance was noted and the weights obtained are within the normal range observed for control animals. The stimulation indices for the lymph node cell counts were 1.098, 1.170, and 1.045 for 10%, 25%, and 50% test material, respectively. The stimulation indices for the ear weights were 1.037, 1.043, and 1.049 for 10%, 25%, and 50% test material, respectively. The stimulation indices for the lymph node cell count, lymph node weight, and ear weight were 1.461, 1.517, and 1.238, respectively, for the positive control. FeNaEDTA was not a dermal sensitizer. The present study does not meet the guideline requirements of OPPTS 870.2600, but was compliant with OECD TG 429 (2002). The packet is classified as **ACCEPTABLE,** although the local lymph node assay procedure "was never validated for mixtures by the assay creators. It is undergoing a validation step through ICCVAM - which is a lead NIEHS group of all gov't agency."

DATA EVALUATION RECORD

SLUGKIL MP (FENAEDTA)

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (870.1300)
MRID 47942512

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
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Prepared by
Toxicology and Hazard Assessment Group
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Oak Ridge, TN 37831
Task Order No. 10-004

Primary Reviewer:
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Robert H. Ross, M.S., Group Leader

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Date: JUN 10 2010

Quality Assurance:
Eric Lewis, M.S.

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Date: JUN 10 2010

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Acute Inhalation Toxicity - Rats (OPPTS 870.1300)
MRID NO:	47942512
DP BARCODE NO:	DP 373965
DECISION NO:	425379
SUBMISSION NO:	866101
TEST MATERIAL:	FeNaEDTA (EPA Reg. No. 67702-GR, ethylenediaminetetraacetic acid iron (III) sodium salt, containing 69.9% EDTA, a.i.)
PROJECT NO:	21619 (Report No.)
SPONSOR:	Neudorff GmbH KG, Postfach 1209, An der Mühle 3, D-31860 Emmerthal, Germany
TESTING FACILITY:	LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, P.O. Box 920461, D-21134 Hamburg, Germany
TITLE OF REPORT:	Inhalation
AUTHOR:	Dr. J. Haferkorn
STUDY COMPLETED:	January 8, 2008
GOOD LABORATORY PRACTICE:	GLP Compliant, according to EC method B.2 (92/69/EEC) and OECD guideline 403
CONCLUSION:	The inhalation LC_{50} for males, females, and combined sexes was > 2.75 mg/L.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY IV

I. STUDY DESIGN:

1. **Test Material:** FeNaEDTA - ethylenediaminetetraacetic acid iron (III) sodium salt, Batch No. 080 507, containing 69.9% EDTA, a.i.

2. **Test Animals:** Five male and five female CD/Crl:CD(SD) rats were received from Charles River Laboratories, Research Models and Services, Germany GmbH, Sandhofer Weg 7, 97633 Sulzfeld, Germany and weighed 228-250 g (males) and 214-241 g (females) on the day of exposure. The young adult animals, 51-65 days old, were housed in groups of 2-3 per sex in Makrolon cages (type III). The animals were fed commercial diet, ssniff® R/M-H V 1534 (ssniff Spezialdiäten GmbH, 59494 Soest, Germany). Drinking water in bottles was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 22±3°C; relative humidity, 55±15%; and air changes, 12-18 per hour; photoperiod, 12 hour light/dark cycle.

3. **Methods:** Rats were identified by colored marks and cage labels: Male – Nos. 1m to 5m; Female – Nos. 6f to 10f. The rats were acclimated for at least 5 days prior to exposure. The animals were exposed to the concentration shown in Table 1. The test material was dissolved in water as a 5.7% solution (approximately limit of solubility). The rats were exposed nose-only in a dynamic flow inhalation chamber for four hours. The animals were observed at 0, 5, 15, 30, and 60 minutes, and 3 hours after exposure and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on test days 8 and 15. All rats were sacrificed and necropsied at the end of the study.

TABLE 1. Concentrations, exposure conditions, mortality/animals treated

Nominal Conc. (µL/L)	Grav. Conc. (mg/L)	MMAD (µm)	GSD (µm)	Particles ≤4 µm (%)	Temp (°C)	Humidity (%)	Mortality		
							Male	Female	Combined
55.56	2.75	2.730	5.20	44.1	20.9-22.0	Not reported	0/5	0/5	0/10

Data taken from pp. 22, 24, 28, 29, 30, and 31, MRID 47942512.

Generation of the test atmosphere and description of the chamber: Prior to aerosolization, the test material was dissolved in water to a 5.7% solution (approximately limit of solubility). The exposure atmosphere was generated using a spray-jet (Type 970, Düsen-Schlick GmbH, 96253 Untersiemau, Germany). The spay-jet was fed with compressed air at 5.0 bar from a compressor and with the test material using an infusion pump. The oxygen content in the chamber was 21%. The air flow entrance and flow exit were 900 and 800 L/h, respectively, to produce a homogenous distribution and a positive pressure in the chamber. There were 22.5 air changes per hour. The nose-only cylindrical exposure chamber volume was 40 L with an equilibration time of 15 min.

Test atmosphere concentration: During exposure, gravimetric samples were collected using an air sample filter from the breathing zone of the animals once every hour during exposure. Filters were weighed before and after sampling. Before weighing the filters were

dried for 30 minutes at 100°C. The nominal and the actual concentrations were reported, but no explanations of calculation were given.

Particle size determination: Particle size for exposure concentration was determined twice using an eight-stage cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter was estimated by means of non-linear regression analysis. The geometric standard deviation was calculated from the quotient of the 84%- and the 50%-mass fractions, obtained from the non-linear regression analysis. Result are in Table 1 above.

II. RESULTS:

1. **Mortality:** All rats survived the study.

2. **Clinical Observations:** No signs of toxicity were noted during the study.

3. **Body Weight:** All rats gained weight during the study.

4. **Gross Necropsy:** No pathological findings were noted at necropsy.

III. DISCUSSION:

The inhalation LC_{50} for males, females, and combined sexes was > 2.75 mg/L. This places FeNaEDTA in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

SODIUM FERRIC EDTA
(Slugkil MP)

STUDY TYPE: Summary of Published Toxicology Data (Nonguideline)

MRID 47942517

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 10-004

Primary Reviewer:
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Date: JUN 10 2010

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:	
STUDY TYPE:	Summary of Published Toxicology Data (Nonguideline)
MRID NO:	47942517
DECISION NO:	425379
DP BARCODE:	DP373965
TEST MATERIAL:	Slugkil MP (a.i., 71.42% w/w sodium ferric EDTA)
PROJECT STUDY NO:	None
SPONSOR:	W. Neudorff GmbH KG, An der Muhle 3, 31860 Emmerthal, Germany
TESTING FACILITY:	Not appplicable
TITLE OF REPORT:	Compilation of Toxicology Data
AUTHOR:	Talerek, W.G.
STUDY COMPLETED:	November 30, 2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The submitter was neither the sponsor of the study nor conducted it, and does not know if it was conducted in accordance with 40 CFR Part 160.
CONCLUSION:	The information provided indicates that the components of sodium ferric EDTA are not likely to produce adverse toxic effects at exposure levels expected from the recommended use of the product. However, a conclusion for sodium ferric EDTA itself cannot be drawn.
CLASSIFICATION:	Supplemental.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Introduction

Slugkil MP is a manufacturing use product to be used to formulate end use product molluscicides intended for home and garden, commercial, and agricultural use. The active ingredient in the product is 71.42% w/w sodium ferric EDTA. The inert ingredient is [redacted].

MRID 47942517 is a compilation of published literature related to the toxicology of the components of sodium ferric EDTA. Relevant portions of each of the publications are summarized below.

Summary of Literature

Candela, E., M.V. Camacho, C. Martinez-Torres, et al. 1984. Iron Absorption by Humans and Swine from Fe(III)-EDTA. Further Studies. J. Nutr. 114:2204-2211.

Six human subjects drank a solution containing 5 mg of Fe as Fe(III)-EDTA labeled with ^{59}Fe. Urine was collected over 48 hours, and blood was drawn 15 days later. Mean iron absorption was 12.0%, and elimination via urine was 0.3%. The greatest amount of iron eliminated in the urine occurred during the first 24 hours.

Sixteen male pigs were fed a commercial feed containing $Na^{55}Fe$-[2-^{14}C]EDTA and maintained in metabolic cages. About 5% of the ^{55}Fe was absorbed from the pylorus and upper jejunum and transferred very slowly to the plasma, where it was incorporated into the hemoglobin. Less than 1% was excreted by the kidneys. The remainder was excreted in the feces, mostly in an insoluble form. About 5% of the administered ^{14}C was absorbed in the duodenum and jejunum, transferred to the plasma, and excreted by the kidneys. The remainder was excreted in the feces, about 80% in a soluble form.

Dunkel, V.C., R.H.C. San, H. E. Seifried, et al. 1999. Genotoxicity of Iron Compounds in *Salmonella typhimurium* and L5178Y Mouse Lymphoma Cells.

NaFeEDTA was positive for mutagenicity in the L5178Y TK +/- Mouse Lymphoma Assay in both the absence and presence of S9. The range of test concentrations was 1.3-325 µg Fe/mL without S9 and 0.26-6.5 µg Fe/mL with S9.

Gasset, A.R. and T. Akaboshi. 1977. Embryopathic Effect of Ophthalmic EDTA. Invest. Ophthalmol. Visual Sci. 16(7):652-654.

Pregnant adult albino rabbits received two drops of 0.1% or 3.0% EDTA solution in each eye six times per day from the sixth to the eighteenth day of gestation. On gestation day 29, they were sacrificed and the fetuses were removed for external and histological examination. Although no teratological effect was found at either dose, the 3.0% dose produced an embryopathic effect, with only 30% of the progeny classified as normal.

Heimbach, J., S. Rieth, F. Mohamedshah, et al. 2000. Safety Assessment of Iron EDTA [Sodium Iron (Fe^{3+}) Ethylenediaminetetraacetic Acid]: Summary of Toxicological, Fortification, and Exposure Data. Food and Chemical Toxicology 38:99-111.

Iron EDTA dissociates in the gastrointestinal tract to iron and an EDTA salt, each of which is absorbed independently. The available evidence suggests that normal individuals are able to control the absorption of iron despite high intakes. EDTA compounds are poorly absorbed from the gastrointestinal tract and have a low acute oral toxicity. They have not been found to have reproductive or developmental toxicity when administered orally along with nutritionally adequate diets. In chronic toxicity studies, no adverse effects were seen at 5% EDTA in the diet. EDTA compounds have not been found to be carcinogenic or directly genotoxic. Historical data demonstrate that iron EDTA is safe and effective when used to fortify food products, and meets the standard of "reasonable certainty of no harm."

The authors note that the positive result for mutagenicity for NaFeEDTA found in the mouse lymphoma test by Dunkel et al. (1999) described above most likely reflected the sensitivity of the L5187Y cells to abnormal iron concentrations, and conclude that EDTA-metal complexes lack significant genotoxic potential.

Kimmel, C.A. 1977. Effect of Route of Administration on the Toxicity and Teratogenicity of EDTA in the Rat. Toxicology and Applied Pharmacology 40:299-306.

The toxic and teratogenic effects of EDTA in rats were determined after it was administered either in the diet (954 mg/kg/day), by gastric intubation (625 mg/kg twice a day or 750 mg/kg twice a day), or subcutaneously (375 mg/kg). The treatments were applied on gestation days 7 through 14 and the animals were sacrificed on gestation day 21. EDTA in the diet produced severe maternal toxicity and malformations in 71% of the offspring. EDTA by intubation resulted in 36% maternal death at 625 mg/kg twice daily and 87.5% maternal death at 750 mg/kg twice daily. At 625 mg/kg twice daily, the malformation rate was 20.5%. The subcutaneous route produced 24% lethality in dams and 4.3% malformations in the offspring.

McGregor, D.B., A. Brown, P. Cattanach, et al. 1988. Responses of the L5178Y tk^+/tk^- Mouse Lymphoma Cell Forward Mutation Assay: III. 72 Coded Chemicals. Environmental and Molecular Mutagenesis 12:85-154.

EDTA, trisodium salt, at concentrations up to 5000 µg/mL did not produce mutagenic responses with or without added S9.

National Cancer Institute. 1977. Bioassay of Trisodium Ethylenediaminetetraacetate Trihydrate (EDTA) for Possible Carcinogenicity. DHEW Publication No. 77-811. NTIS, Springfield,VA.

Concentrations of 3750 or 7500 ppm $Na_3EDTA\text{-}3H_2O$ were administered in the diet to Fischer 344 rats and B5C3F1 mice for 103 weeks. There were no treatment-related signs of clinical toxicity, and mortality was similar among the treatment and control groups. The test material produced no evidence of carcinogenicity in this study.

Oser, B.L., M. Oser, and H.C. Spencer. 1963. Safety Evaluation Studies of Calcium EDTA. Toxicology and Applied Pharmacology 5:142-162.

CaEDTA (50, 125, or 250 mg/kg body weight) was fed in the diet to groups of male and female Wistar rats for up to two years. After approximately 13 weeks, the rats were mated and the offspring were raised on their respective parents' diets. This was repeated for two additional generations. There were no adverse effects on growth, food efficiency, or hematology parameters on the F_0 generation or the three succeeding generations maintained on the same diet. There were no adverse effects on reproduction or lactation efficiency, and no treatment-related gross or microscopic findings.

Additionally, groups of mongrel dogs were administered diets containing 50, 100, or 250 mg CaEDTA/kg body weight for up to one year. All dogs survived and gained weight. There were no significant deviations from control values for urine or blood chemistry parameters. Gross and histopathologic results were unremarkable.

Swenerton, H. and L.S. Hurley. 1971. Teratogenic Effects of a Chelating Agent and Their Prevention by Zinc. Science 173:62-63.

A diet containing 3% EDTA fed to groups of female Sprague-Dawley rats during gestation days 6-21 produced gross congenital malformations in all the full-term young. These effects were prevented by supplementing the 3% EDTA diet with 1000 ppm zinc during gestation days 6-21.

World Health Organization. 2005. Sodium Iron EDTA. WHO Food Additives Series 32.

The Joint FAO/WHO Expert Committee on Food Additives (JEFCA) provisionally concluded that use of sodium iron EDTA in supervised food fortification programs in iron-deficient populations does not present a safety problem. The Committee requested that additional studies be conducted to assess the deposition site of iron administered in this form and to assess the metabolic fate of sodium iron EDTA following long-term administration.

World Health Organization. 2000. Sodium Iron Ethylenediamine Tetraacetic Acid (EDTA). WHO Food Additives Series 4.

JEFCA concluded that sodium iron EDTA could be considered safe for use in supervised food fortification programs when public officials had determined the need for iron supplementation of the diet of a population. Such programs would provide a daily iron intake of approximately 0.2 mg/kg body weight.

Anonymous. 1964. Toxicology of EDTA. Food and Cosmetics Toxicology 2:763-767.

Summary of the thesis, "Toxicological Investigation of Ethylenediaminetetraacetic Acid in the Rat." S-S. Yang. 1952.

A single oral dose of Na_2EDTA in rats produced an LD_{50} of 2.0-2.2 g/kg body weight.

A challenge injection of 0.1 mL of 0.1% Na_2EDTA did not produce an allergic response in guinea pigs two weeks after a series of 10 injections given on alternate days.

There were no deaths in albino rats fed 0.5, 1.0, or 5.0% Na_2EDTA in the diet for 12 weeks. The high-dose group consisted of littermates born of an animal that had been fed a diet containing 0.5% EDTA for eight months. There were no toxic effects, except that the high-dose group suffered continuous diarrhea and consumed less food than the other groups. The test continued for a total time of two years, after which there were no treatment-related changes in growth, food consumption, hematology, or mortality. There were no adverse or gross or microscopic findings.

A separate group of rats on a mineral-deficient diet was fed 0.5 or 1.5% Na_2EDTA or 1.5% $Na_2CaEDTA$ for four months. There was no mortality and all groups exhibited a similar general condition.

Summary of thesis, "Some Toxicological and Physiological Studies of Ethylenediaminetetraacetic Acid in the Albino Rat." M.S. Chan. 1956.

Albino rats on the same mineral-deficient diet as in the Yang study were fed 0.5 or 1.0% Na_2EDTA or 0.1 or 1.0% $Na_2CaEDTA$ for 205 days. Growth of males receiving 1.0% Na_2EDTA and females receiving 1.0% $Na_2CaEDTA$ was retarded. Diarrhea and anemic appearance were noted in the 1.0% Na_2EDTA group. This group also had significantly higher blood coagulation

time, higher blood serum calcium values, and increased dental erosion. There were no appreciable differences at gross or microscopic examination.

In a biochemical study, weanling and adult rats were intubated and administered oral doses equivalent to the 1% dietary levels of Na_2EDTA or $Na_2CaEDTA$. After 48 hours, almost all EDTA was eliminated from the body, mostly (>85%) in the feces. After a single oral dose of 95 mg Na_2EDTA, 93% was recovered in the colon after 32 hours.

Study Author's Conclusions

The study author made no conclusions.

Reviewer's Comments

Most of the information provided was for the individual components of sodium ferric EDTA, not for the compound itself. Generally, the information provided indicates that the components of sodium ferric EDTA are not likely to produce adverse toxic effects at exposure levels expected from the recommended use of the product. However, a conclusion for sodium ferric EDTA itself cannot be drawn.

DATA EVALUATION RECORD

SODIUM FERRIC EDTA
(Slugkil MP)

STUDY TYPE: Summary of Published Environmental Fate Data
(Nonguideline)

MRID 47942518

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 10-004

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Date: JUN 10 2010

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:	
STUDY TYPE:	Summary of Published Environmental Fate Literature (Nonguideline)
MRID NO:	47942518
DECISION NO:	425379
DP BARCODE:	DP373965
TEST MATERIAL:	Slugkil MP (a.i., 71.42% w/w sodium ferric EDTA)
PROJECT STUDY NO:	None
SPONSOR:	W. Neudorff GmbH KG, An der Muhle 3, 31860 Emmerthal, Germany
TESTING FACILITY:	Not appplicable
TITLE OF REPORT:	Compilation of Environmental Fate Data
AUTHOR:	Talerek, W.G.
STUDY COMPLETED:	November 30, 2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The submitter was neither the sponsor of the study nor conducted it, and does not know if it was conducted in accordance with 40 CFR Part 160.
CONCLUSION:	The information provided indicates that sodium ferric EDTA would likely be slowly degraded by photolysis and/or naturally-occurring microorganisms in surface waters and by naturally-occurring microorganisms in agricultural soils.
CLASSIFICATION:	Supplemental.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Introduction

Slugkil MP is a manufacturing use product to be used to formulate end use product molluscicides intended for home and garden, commercial, and agricultural use. The active ingredient in the product is 71.42% w/w sodium ferric EDTA. The inert ingredient is [redacted].

MRID 47942518 is a compilation of published literature related to the environmental fate of components of sodium ferric EDTA. Relevant portions of each of the publications are summarized below.

Summary of Literature

Belly, R.T., J.J. Lauff, and C.T. Goodhue. 1975. Degradation of Ethylenediaminetetraacetic Acid by Microbial Populations from an Aerated Lagoon. Applied Microbiology 29(6):787-794.

This paper reports microbial degradation of the sodium- or ammonium-ferric chelate of EDTA (Na- or NH_4Fe-EDTA) by mixed populations of microorganisms present in an aerated industrial lagoon. A radiorespirometric technique showed that 27% of the acetate-2-C and 31% of the ethylene position of the ammonium ferric chelate of ^{14}C-EDTA were recovered as $^{14}CO_2$ after

five days of incubation. In a separate test using the sodium ferric chelate, gas liquid chromatography and total organic carbon analyses showed 89% and 63% reductions of EDTA, respectively, over a similar period. $^{14}CO_2$ evolution was strongly inhibited by heat treatment of the samples or by the addition of antibiotics to the incubation mixtures. Possible intermediates of EDTA degradation were identified using mass spectral analysis.

Bucheli-Witschel, M. and T. Egli. 2001. Environmental Fate and Microbial Degradation of Aminopolycarboxylic Acids. FEMS Microbioloy Reviews 25:69-106.

Biodegradation is apparently of minor importance for EDTA in the environment. Thermic hydrolysis and indirect photolysis have negligible effects. Direct photodegradation of iron (III)-complexed EDTA appears to be mostly responsible for its elimination. Reported half-lives in surface waters ranged from 11.3 minutes to >100 hours. Negligible adsorption has been reported for EDTA on humic acids, silica, kaolin, river sediments, humus solids, and activated sludge particles. While reports have described biologically-mediated degradation of EDTA under laboratory conditions, there has been no indication for significant elimination in municipal wastewater treatment plants. Reports of EDTA degradation in soils and sediments have been contradictory. Successful isolation of EDTA-degrading bacteria, including *Agrobacterium radiobacter* and *Mesorhizobium loti*, has been reported.

Dyanand, S. and M.K. Sinha. 1979. Kinetics of FeEDTA Reactions in Calcareous Soils. Soil Science 127(4):202-210.

In a laboratory test, kinetics of the reaction of FeEDTA with seven soils having a wide range of $CaCO_3$ content (0-22%) was studied. During the first 2-72 hours, the reaction followed first-order kinetics. When FeEDTA reacted with the soils, the EDTA ligands formed complexes with other cations in the soil solution. CaEDTA was initially the dominant species formed, while ZnEDTA and CuEDTA also formed as the reaction time increased.

Frank, R. and H. Rau. 1990. Photochemical Transformation in Aqueous Solution and Possible Environmental Fate of Ethylenediaminetetraacetic Acid (EDTA). Ecotoxicology and Environmental Safety 19:55-63.

Since EDTA is not volatile, it is released into the environment mainly via wastewater. In wastewater treatment plants, EDTA is not transformed by microorganisms or adsorbed to sewage sludge. It is believed that most of the EDTA in surface waters is present in the form of Fe(III) complexes. The removal of EDTA from surface waters can occur via photochemical reactions of the FeEDTA complex. Using optical absorption coefficients of the FeEDTA spectrum at pH 7, quantum yields at pH 7, and an oxygen content near the air-saturated value, the mean half-life of FeEDTA in the Neckar River in Germany was estimated to range from 5 to 480 hours. Degradation of the FeEDTA was fastest during the summer months. Other abiotic transformation processes for FeEDTA could be reactions with OH radicals and singlet oxygen, but these processes are likely to be minor.

FeL^- and CaL^{2-} are again the predominant complexes at low and high pH, but ZnL^{2-} becomes the major complex between pH 6 and 7.

Lockhart, Jr., H.B. and R.V. Blakeley. 1975. Aerobic Photodegradation of Fe(III)-(Ethylenedinitrilo)Tetraacetate (Ferric EDTA). Environ. Sci. Technol. 9:1035-1038.

Photodegradation of aqueous solutions of ferric-1-^{14}C-EDTA at pH 4.5, 6.9, and 8.5 was investigated under irradiation from a wide-spectrum xenon arc lamp. The rate of photodegradation was pH-dependent, and was most rapid at pH 4.5. At a light intensity of 4000 foot candles and an initial Fe(III)-EDTA concentration of 0.0016M, EDTA was completely removed after 24 hours of irradiation at pH 4.5 or 6.9, and after 32 hours at pH 8.5. Major photodegradation products included carbon dioxide, formaldehyde, N-carboxy-methyl N,N'-ethylenediglycine (ED3A), N,N'-ethylenediglycine (EDDA-N,N'), iminodiacetic acid (IMDA), N-carboxymethyl-N-aminoethyleneglycine (EDDA-N,N'), N-aminoethyleneglycine (EDMA), and glycine.

Metsarinne, S., T. Tuhkanen, and R. Aksela. 2001. Photodegradation of Ethylenediaminetetraacetic Acid (EDTA) and Ethylenedaimine Disuccinic Acid (EDDS) within Natural UV Radiation Range. Chemosphere 45:949-955.

Photodegradation of Fe(III)-EDTA and Fe(III)-EDDS in humic lake water or distilled water exposed to sunlight or artificial light (UV radiation at 315-400 nm) was investigated at an initial pH of 3.1 or 6.5. Under artificial light at pH 3.1, the half life of Fe(III)-EDTA was 14.0 minutes in distilled water and 31.1 minutes in lake water. At pH 6.5, the half life was 45.0 minutes in distilled water and 56.8 minutes in lake water. Under sunlight at pH 6.5, Fe(III)-EDTA degraded completely after one week in either distilled or lake water. At pH 3.1, it degraded completely after one day in distilled water and two days in lake water.

Svenson, A., L. Kaj, and H. Bjorndal. 1989. Aqueous Photolysis of the Iron (III) Complexes of NTA, EDTA and DTPA. Chemosphere 18(9/10):1805-1808.

A ferric EDTA solution was illuminated in a Xenotest 1200 apparatus with a sun spectrum representing daily and yearly maxima at 60°N latitude. The calculated half life in the top millimeters of a body of water in Stockholm under optimum degradation conditions was 42.9 minutes.

Sykora, V., P. Pitter, I. Bittnerova, et al. 2001. Biodegradabilitiy of Ethylenediamine-Based Complexing Agents. Wat. Res. 35(8):2010-2016.

Biodegradation of ethylenediamine derivatives with different kinds and number of substituents were conducted. Initial concentrations of complexing agents were about 100 mg/L, corresponding to 0.34 mmol/L EDTA. The inoculum was either non-adapted or activated sewage sludge from a municipal water treatment plant in Prague. EDTA was among the most stable compounds.

Kari, F.G., S. Hilger, and S. Canonica. 1995. Determination of the Reaction Quantum Yield for the Photochemical Degradation of Fe(III)-EDTA: Implications for the Environmental Fate of EDTA in Surface Waters. Environmental Science & Technology 29(4):1008-1017.

The photochemical reaction quantum yield of Fe(III)EDTA at concentrations <1 μM was determined as a function of wavelength, pH, and temperature. The quantum yield was not influenced by pH, was slightly influenced by temperature, and strongly influenced by wavelength. At wavelengths of 313, 366, and 405 nm (at 25°C), the average quantum yields were 0.082, 0.034, and 0.018, respectively. The quantum yields were used to predict typical photochemical half-lives of Fe(III)EDTA in the Glatt River, Switzerland. The predicted half lives at the water surface ranged from about 15 minutes in June to about 140 minutes in December.

Kunkely, H. and A. Vogler. 1994. Photochemistry of the Oxo-Bridge Diiron(III)Core. Evolution of Oxygen Induced by FE^{III} to Fe^{III} Charge-Transfer Excitation of μ-Oxobis[(Ethylenediaminetetraacetato)Ferrate(III)]. J. Chem. Soc., Chem. Commun.: 2671-2672.

The reversible photolysis of aqueous $[\{Fe^{III}(EDTA)\}_2O]^{4-}$ leads to the evolution of oxygen and the formation of $[Fe^{II}(EDTA)]^{2-}$. This paper suggests that the photoreaction is induced by Fe^{III} to Fe^{III} charge-transfer excitation, which yields Fe^{II} and Fe^{IV}=O in the primary photochemical step.

Lahav, N. and M. Hochberg. 1975. Kinetics of Fixation of Iron and Zinc Applied as FeEDTA, FeEDDHA and ZnEDTA in the Soil. Soil. Sci. Soc. Amer. Proc. 39: 55-58.

In column tests using Rehovot sand, pH 7.1-7.2, the fixation of iron applied as FeEDTA was a first-order reaction. FeEDDHA was not adsorbed, and adsorption of ZnEDTA was negligible.

Lauff, J.J., D. B. Steele, L.A. Coogan, et al. 1990. Degradation of the Ferric Chelate of EDTA by a Pure Culture of an *Agrobacterium* sp. Applied and Experimental Microbiology 56(11):3346-3353.

A pure culture of an *Agrobacterium* that mineralizes ferric-EDTA was isolated and grown on ferric-EDTA as the sole carbon source at concentrations >100 mM. As degradation proceeded, carbon dioxide, ammonia, and an unidentified metabolite(s) were produced, the pH increased, and iron precipitated from solution. When sodium ferric EDTA was the substrate, the maximum degradation rate was 24 mM/day. At a substrate concentration of 35 mM, 90% was degraded in three days. Less than 15% of the initial carbon present was incorporated into the cell mass.

Lindsay, W.L. and W.A. Norvell. 1969. Equilibrium Relationships of Zn^{2+}, Fe^{3+}, Ca^{2+}, and H^+ with EDTA and DTPA in Soils. Soil Sci. Soc. Amer. Proc. 33:62-68.

Mole-fraction diagrams were derived for EDTA and DTPA in soils when the competing cations are either Fe^{3+}, Ca^{2+}, and H^+, or Zn^{2+}, Fe^{3+}, Ca^{2+}, and H^+. When the competing cations are Fe^{3+}, Ca^{2+}, and H^+, the major metal complex is FeL^- (where L^- is the free ligand) below pH 6.8 and CaL^{2-} above pH 6.8. The $Fe(OH)L^{2-}$ complex reaches 0.05 mole fraction at pH 6.6 but decreases at both higher and lower pH values. The $FeHL$, $CaHL^-$, and $Fe(OH)_2L^{3-}$ complexes are of less significance in the range of pH 4 to 9. When the competing metals are Zn^{2+}, Fe^{3+}, Ca^{2+}, and H^+,

Thomas, R.A.P., K. Lawlor, M. Bailey, et al. 1998. Biodegradation of Metal-EDTA Complexes by an Enriched Microbial Population. Applied and Environmental Microbiology 64(4):1319-1322.

A mixed culture of microorganisms isolated from samples of River Mersey (UK) water and industrial effluent treatment plant sludge was provided with EDTA as the sole carbon source for 30 days. Organisms included represented *Methylobacterium*, *Variovorax*, *Enterobacter*, *Aureobacterium*, and *Bacillus*. The culture slowly biodegraded metal-EDTA complexes in the order Fe >Cu >Co >Ni >Cd.

Tiedje, J.M. 1975. Microbial Degradation of Ethylenediaminetetraacetate in Soils and Sediments. Applied Microbiology 30(2):327-329.

Agricultural soil and lake sediment samples were incubated under aerobic conditions in flasks with ^{14}C-EDTA (4.0 µg free acid/g soil) or mixed culture medium containing 4.5 µg ^{14}C-EDTA/mL of mineral salts. EDTA chelates of Cu, Cd, Zn, Mn, Ca, and Fe added to the soil were equally degraded; Ni-EDTA was degraded more slowly. Results were similar for the sediment tests.

Tiedje, J.M. 1977. Influence of Environmental Parameters on EDTA Biodegradation in Soils and Sediments. J. Environ. Qual. 6(1):21-26.

Agricultural soil samples representing different origins, textures, uses, and pH were incubated with ^{14}C-labelled EDTA (generally 2.5-4.5 ppm µg free acid/g soil) under aerobic or anaerobic conditions. Sediments from the Detroit River-Lake Erie area were also included in the tests. All the soils and sediment tested slowly degraded the ^{14}C-EDTA to $^{14}CO_2$ under aerobic conditions, but no $^{14}CO^2$ was produced under anaerobic conditions. Degradation appeared to result from co-metabolism by established microbial populations. Degradation was seen up to 1000 ppm EDTA, the highest concentration tested. Soil samples collected in winter produced more than twice the degradation than those collected in summer.

Hill-Cottingham, D.G. and C.P. Lloyd-Jones. 1961. Absorption and Breakdown of Iron-Ethylenediamine Tetraacetic Acid by Tomato Plants. Nature 169:312.

Tomatoes grown in iron-free nutrient solution were transferred to nutrient solution containing 1 ppm iron as FeEDTA. The iron was labeled with Fe-59 and the EDTA with C-14. The plants and nutrient solution were analyzed after 10, 17, and 24 days. After 10 days, 41% of the added iron and 26% of the C-14 were recovered in the plants. After 24 days, nearly all the added iron was recovered from the plants or solutions; recovery of C-14 was about 60%, indicating decomposition of the EDTA.

Study Author's Conclusions

The study author made no conclusions.

Reviewer's Comments

The information provided indicates that sodium ferric EDTA would likely be slowly degraded by naturally-occurring microorganisms in surface waters and agricultural soils.

Decision #: 425379
DP #: (383137)
PRIA
Parent DP #:
Submission #: 882848

DATA PACKAGE BEAN SHEET

Date: 14-Oct-2010

* * * Registration Information * * *

Registration: 67702-GR - SLUGKIL MP

Company: 67702 - W. NEUDORFF GMBH KG

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: John Fournier JFOURN01

Sent Date: 27-Sep-2010 Calculated Due Date: 12-Jan-2011 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (B630) NEW USE;FIRST FOOD USE;MICROBIAL/BIOCHEMICAL WITH EXEMPTION;

Ingredients: 139114, Sodium ferric ethylenediaminetetraacetate(71.42%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 14-Oct-2010 Due Back:

DP Ingredient: 139114, Sodium ferric ethylenediaminetetraacetate

DP Title:

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	BPPD / BPB			Last Possible Science Due Date: 17-Jan-2010
Team Name:	RM 91			Science Due Date: 14-Jan-2011
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Russ,

Please assign the attached data volumes to Clara for secondary review. They are a response to deficiencies identified in the DERs. Please ensure review is completed by 1/14/2011.

Thanks,

John

DP#: (383137) *** * * Studies Sent for Review * * *** Decision#: (425379)

MRID	MRID Status	Citation Reference	Guideline
48240703		Stewart, C.; Almond, D. (2010) Slugkil MP: Physical/Chemical Properties. Unpublished study prepared by Eco-Care Technologies, Inc. 33 p.	830.6317/Storage stability
48240701		Almond, D.; Stewart, C. (2010) Slugkil MP: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 21 p.	880.1100/Product identity and composition
48240701		Almond, D.; Stewart, C. (2010) Slugkil MP: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 21 p.	880.1200/Description of starting materials, production and formulation process
48240702		Witteveen, A. (2002) Slugkil MP: Product Chemistry: Melting Point/Melting Range. Project Number: MEMORANDUM/CPP/M0202. Unpublished study prepared by AKZO Nobel. 9 p.	830.7200/Melting point/melting range
48240704		Stewart, C.; Almond, D. (2010) Slugkil MP - TGAI: Physical/Chemical Properties. Unpublished study prepared by Eco-Care Technologies, Inc. 17 p.	830.6304/Odor
48240703		Stewart, C.; Almond, D. (2010) Slugkil MP: Physical/Chemical Properties. Unpublished study prepared by Eco-Care Technologies, Inc. 33 p.	830.7000/pH
48240704		Stewart, C.; Almond, D. (2010) Slugkil MP - TGAI: Physical/Chemical Properties. Unpublished study prepared by Eco-Care Technologies, Inc. 17 p.	830.6302/Color
48240700		W. Neudorff GmbH KG (2010) Submission of Product Chemistry Data in Support of the Application for Registration of Slugkil MP. Transmittal of 5 Studies.	
48240701		Almond, D.; Stewart, C. (2010) Slugkil MP: Product Chemistry: Product Identity and Composition. Unpublished study prepared by Eco-Care Technologies, Inc. 21 p.	880.1400/Discussion of formation of impurities
48240705		Henning, H.; Morello-Marano, M. (2001) Slugkil MP: Product Chemistry: Standard Method of Analysis: Determination of the pH of a 1% Solution. Unpublished study prepared by AKZO Nobel. 7 p.	830.7000/pH
48240703		Stewart, C.; Almond, D. (2010) Slugkil MP: Physical/Chemical Properties. Unpublished study prepared by Eco-Care Technologies, Inc. 33 p.	830.6320/Corrosion characteristics

Please read instructions on reverse before completing form. Form Approved 3 No. 2070-0060 Print Form

EPA United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☐ Amendment ☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702-GR	Linda Hollis	☒ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Slugkil MP	91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☒ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Resubmission in response to Data Evaluation Record on MRIDs 47942501-06. See the enclosed letter to Ms. Linda Hollis, PM 91, for a full explanation of the resubmission.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Walter G. Talarek	Authorized Agent
4. Typed Name	**5. Date**
Walter G. Talarek	September 27, 2010

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

TRANSMITTAL DOCUMENT

1. Name and address of submitter

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

2. Regulatory action in support of which this package is submitted

Resubmission in support of application for registration of Slugkil MP, EPA File Symbol 67702-GR, and in response to Data Evaluation Record on MRIDs 47942501-06

3. Transmittal date

September 27, 2010

4. List of submitted studies

Volume 1	Administrative Materials Letter to Ms. Hollis explaining resubmission EPA Form 8570-1 EPA Forms 8570-4: CSFs for Basic Formulation and Alternate Formulations ##1-4 Labels (5 copies) Correspondence Document: Explanations and Waiver Requests
Volume 2	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
Volume 20	Product Chemistry: Melting Point/Melting Point Range, color and odor of TGAI; OPPTS 830.7200
Volume 21	Product Chemistry: Storage Stability, Corrosion Characteristics and pH of Slugkil MP; OPPTS 830.6317, 830.6320 and 830.7000
Volume 22	Product Chemistry: Color and Odor of TGAI: OPPTS 830.6302 and 830.6304
Volume 23	Product Chemistry: Analytical Method for Determination of pH of TGAI; OPPTS 830.7000

Company Official: Walter G. Talarek, Authorized Agent — Signature

Company Name: W. Neudorff GmbH KG

Company Contact: Walter G. Talarek (Name) — (703) 759-4837 (Phone)

Registration Details

Company: 67702 W. NEUDORFF GMBH KG

Risk Mgr: RM 91 Biologicals & Pollution Prevention Division, PM Team 91 ...

Organization: BPPD / BPB ...

Current Status: Under Review (28-Dec-2009)

Reg. Number: 67702-GR Pesticide Type: Biochemical High Exposure? ☐

Use Type: Signal Word:

Repack: ○ Yes ◉ No Latest Approved Label:

IPIC Phone: ○ Yes ◉ No No Ingredient? ☐ WPS Written Notification: ○ Yes ◉ No

WPS-PPE

Label Image

Container Info

Tracking

Status

Sites/Pests

CSF

Data Requirements

Generate Rqmts

Inert Ingredients

Related Products | Restricted Use | Reg. Expiration Date

Use Patterns | Transfer History | Toxicology | Mode Of Action | FR Notice | Receipts

Product Name | Ingredient | Formulation Property | Pesticide Category | Permitted State

Product Name	Name Status
SLUGKIL MP	Active

DEC 2 5 2010

Record
JAN 2 6 2010

ACB 153

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 5, 2010

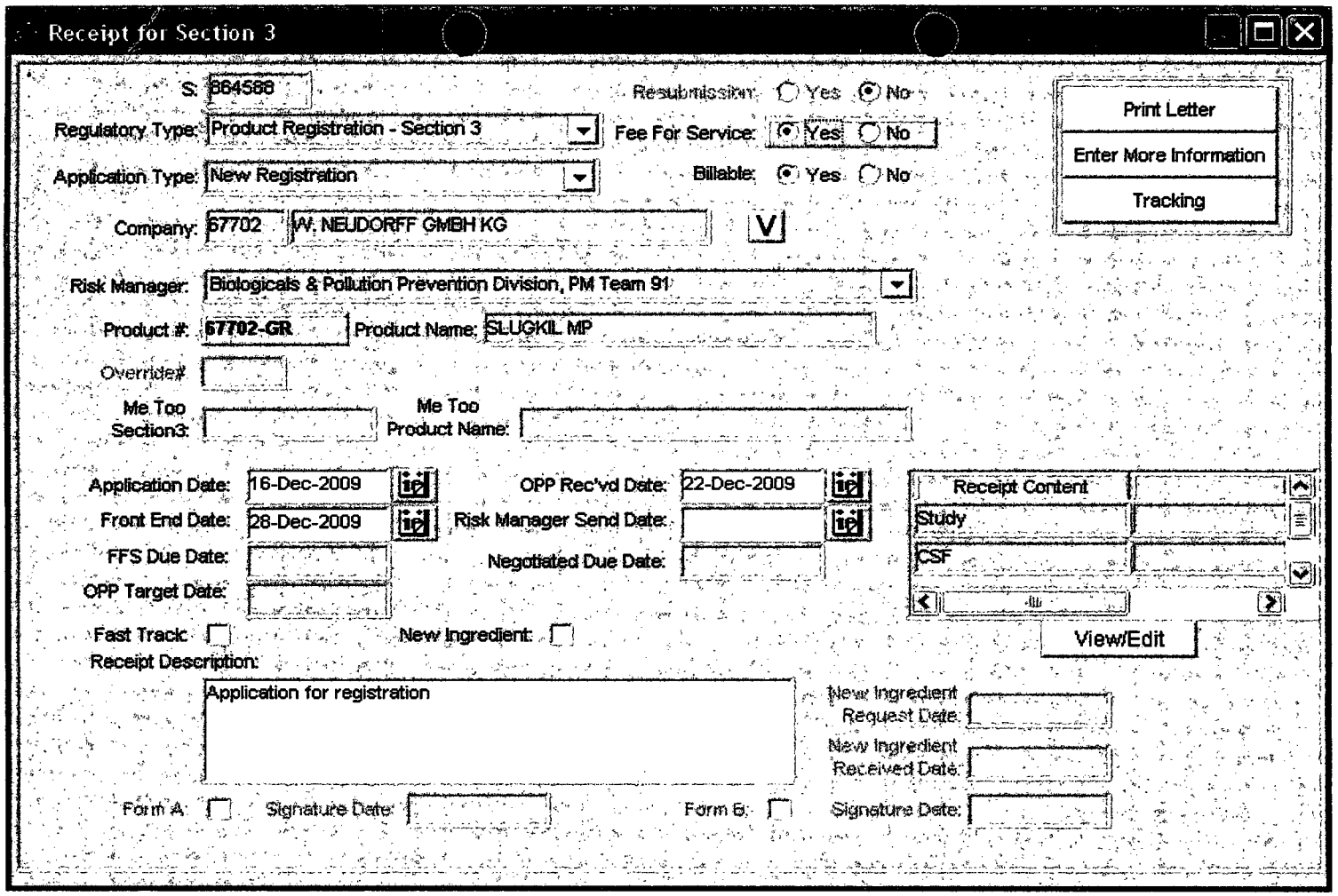
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

W. NEUDORFF GMBH KG
POSTFACH 1209
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 22-DEC-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Decis #425379 B630 12 month time Frame

FFS start Date: 1|12|2010

PRIA Due date: 1|12|2011

Phase I due: 1|27|10

Phase II : 2|27|10

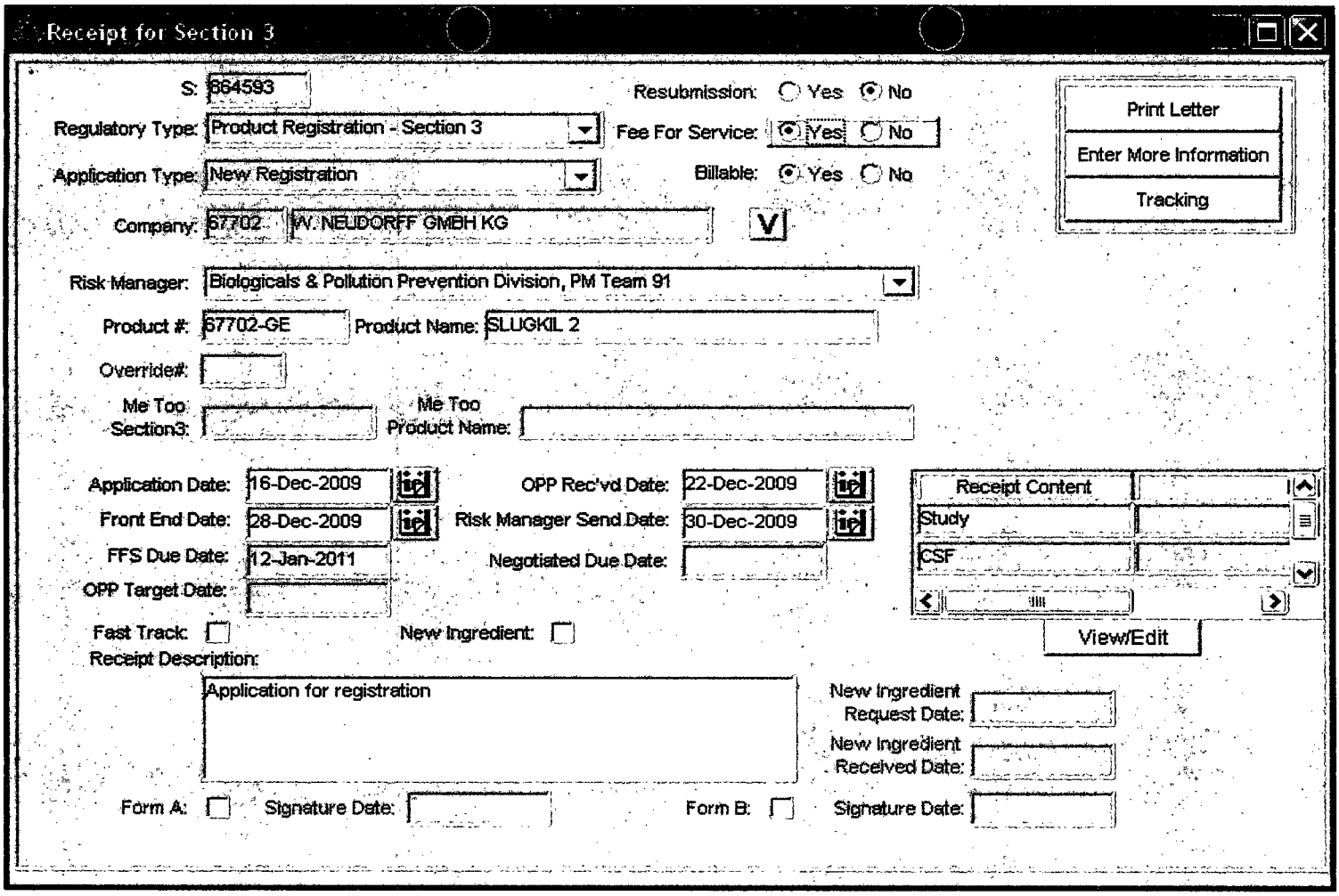
Phase III : 4|27|10

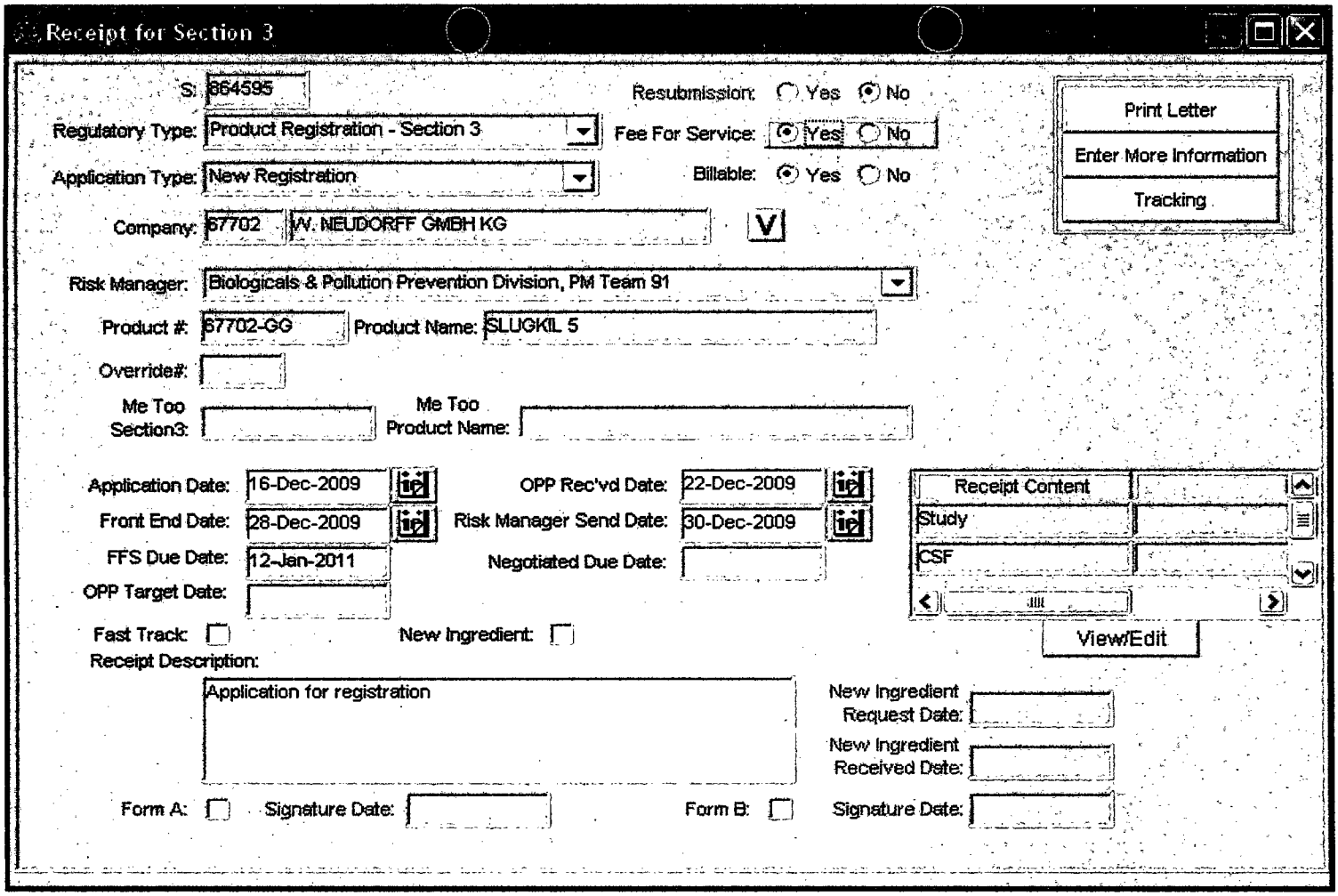
Phase IV : 8|27|10

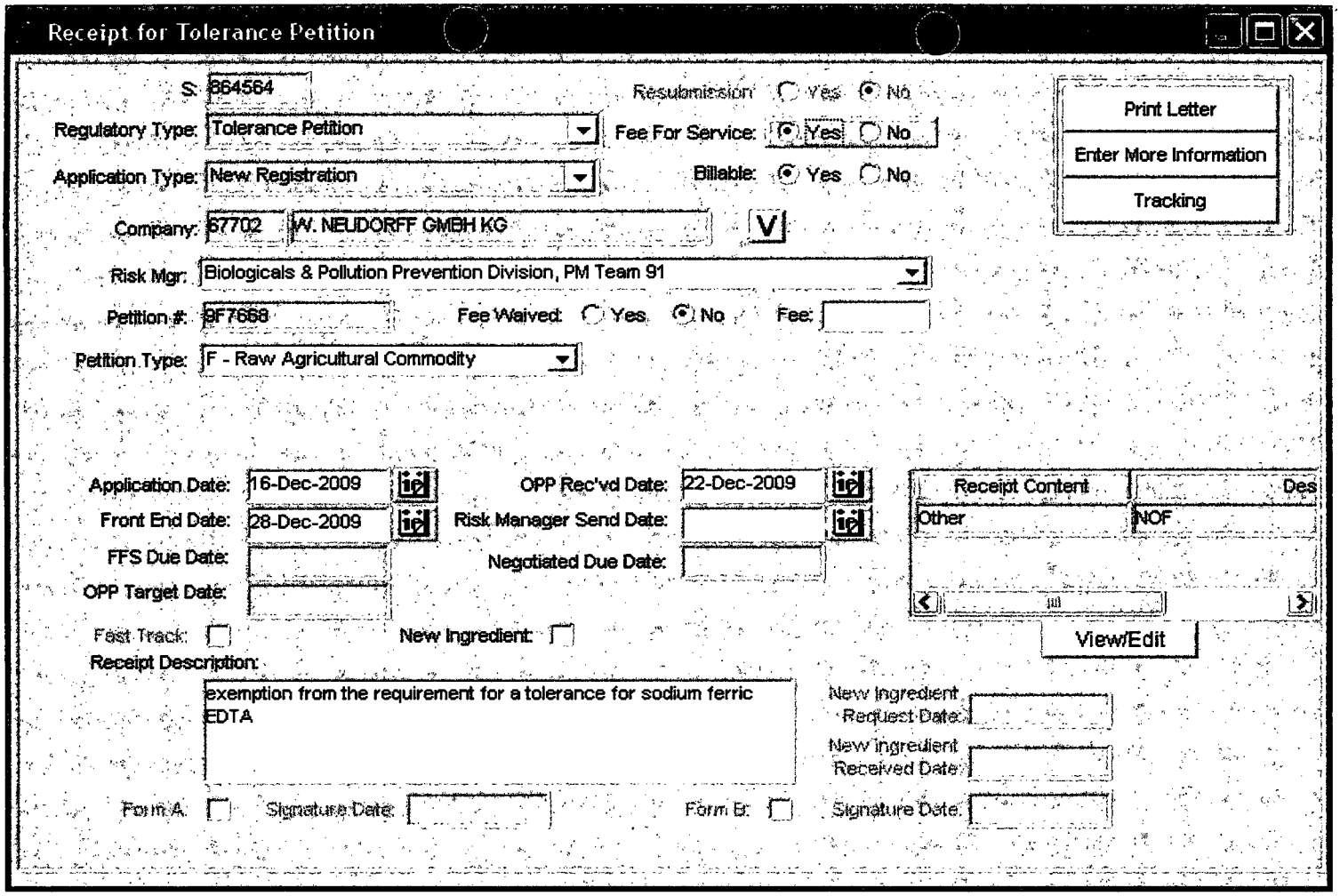
Phase V Docs. 11|11|10

Phase V Dec. 12|12|10

Recvd
1/8/2010
ACB


Receipt for Section 3
S: 864593
Resubmission: Yes No
Print Letter
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Enter More Information
Application Type: New Registration
Billable: Yes No
Tracking
Company: 67702 W. NEUDORFF GMBH KG
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GE
Product Name: SLUGKIL 2
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 16-Dec-2009
OPP Rec'vd Date: 22-Dec-2009
Front End Date: 28-Dec-2009
Risk Manager Send Date: 30-Dec-2009
FFS Due Date: 12-Jan-2011
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
View/Edit
Fast Track:
New Ingredient:
Receipt Description:
Application for registration
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:


Receipt for Section 3
S: 864595
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 67702 W. NEUDORFF GMBH KG
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GG
Product Name: SLUGKIL 5
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 16-Dec-2009
OPP Rec'vd Date: 22-Dec-2009
Front End Date: 28-Dec-2009
Risk Manager Send Date: 30-Dec-2009
FFS Due Date: 12-Jan-2011
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
View/Edit
Fast Track:
New Ingredient:
Receipt Description:
Application for registration
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:



Decis # 425382

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

December 16, 2009

DELIVERED BY COURIER
Linda Hollis, PM 91
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
c/o Document Processing Desk (APPL)(REGFEE)
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Applications for Registration
Slugkil MP; Slugkil 5; and Slugkil 2
W. Neudorff GmbH KG

Dear Ms. Hollis:

On behalf of W. Neudorff GmbH KG ("Neudorff"), I am submitting three (3) applications for registration of products containing sodium ferric EDTA (CAS Reg. No. 15708-41-5) as the sole active ingredient. The first product is Slugkil MP, which is a manufacturing-use product used to formulate the second and third products, whose brand names are Slugkil 2 and Slugkil 5. These latter two products are end-use molluscicidal products intended for home and garden, commercial and agriculture uses as a protective barrier around vegetables, fruits, berries, herbs, field crops, outdoor ornamentals, greenhouses, and on lawns, commercial turf, sod, golf courses, and certain non-crop barrier areas. The two end-use products are applied by hand or standard broadcast or granular spreaders. The end-use products contain the active ingredient at 2% and 5%, respectively.

These applications are primary and secondary new product applications to which PRIA fees apply. All three applications rely on the generic data that are being submitted with the application for registration of Slugkil MP, which is the primary application. In addition, acute toxicity data is being submitted with the application for registration of Slugkil 5. Neudorff submits that the applicable PRIA fee categories for the Slugkil MP, Slugkil 2 and Slugkil 5 applications are B630, B630.1 and B630.2, respectively, because the applications concern the first food uses of an old active ingredient and a petition to establish a tolerance exemption is being submitted. As such, Neudorff believes that the applicable PRIA fee is $18,192, a check for which has been sent today to EPA's Washington Finance Center in St. Louis, MO.

Neudorff is using the selective method to address both the generic and product-specific data requirements applicable to the registrations of Slugkil MP, Slugkil 2 and Slugkil 5. Neudorff is submitting data or data waiver requests to fulfill each of the data requirements applicable to the registrations of

the three products. As stated above, the generic data are being submitted with the application for registration of Slugkil MP, and the applications for registration of Slugkil 2 and Slugkil 5 cite these data. The application for registration of Slugkil MP contains product-specific product chemistry and generic acute toxicology data that is being used through waiver (bridging) requests to address the product-specific acute toxicology data requirements. The application for registration of Slugkil 5 contains product-specific product chemistry and acute toxicology data. The application for registration of Slugkil 2 contains product-specific product chemistry data. The acute toxicology data requirements applicable to the registration of Slugkil 2 are being addressed by citing the acute toxicology data being submitted with the Slugkil 5 application for registration and requesting waivers (bridging).

The data requirements for which waivers are being requested are addressed in the document titled "Correspondence Document: Explanations and Waiver Requests" that is being submitted with each application. Scientific rationales for the waiver requests are provided in this document. The scientific rationales for the generic data requirements waiver requests, for the most part, have been taken from EPA's "Biopesticides Registration Action Document [on] Sodium Ferric Ethylenediaminetetraacetate (PC Code 139114)" (November 20, 2008).

Because the applications for registration of Slugkil 2 and Slugkil 5 involve food crop uses, Neudorff is submitting a petition for an exemption from the requirement for a tolerance. Two copies of the petition are being submitted separately to EPA's Document Processing Desk. One copy of the petition is being submitted with each application for registration of Slugkil MP, Slugkil 2 and Slugkil 5. Similarly, copies of Neudorff's summary of the information, data and arguments in support of its petition, i.e., a completed template titled "EPA Biopesticides and Pollution Prevention Division Company Notice of Filing for Pesticide Petitions Published in the Federal Register", are being submitted to EPA's Document Processing Desk with the petition and with the applications for registration of Slugkil MP, Slugkil 2 and Slugkil 5. Both hard copies and electronic copies of the petition summary are being submitted to the Document Processing Desk with the petition and with the three applications for registration.

When you review the studies being submitted with the applications for registration of Slugkil 2 and Slugkil 5, please note that the test substance NEU1182 is the code name for Slugkil 5 and the test substance NEU1183 is the code name for Slugkil 2.

Five (5) copies of each product's label are enclosed. When you review the Slugkil 2 and Slugkil 5 applications, please note these products' labels are master labels that are divided into two sub-labels: one sub-label is for the home and garden use; and the other sub-label is for the commercial and agriculture uses.

If you have any questions about these applications for registration, please feel free to call me.

Sincerely yours,

Walter G. Talarek
Authorized Agent

Enclosures – Applications for Registration (3)

TRANSMITTAL DOCUMENT

1. Name and address of submitter

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

2. Regulatory action in support of which this package is submitted

Application for registration of Slugkil MP.

3. Transmittal date

December 16, 2009

4. List of submitted studies

	Volume 1	Administrative Materials
47942501	Volume 2	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
47942502	Volume 3	Product Chemistry: Analysis and Certification of Product Ingredients (OPPTS 830.1700, 830.1750 and 830.1800)
47942503	Volume 4	Product Chemistry: Physical and Chemical Characteristics (OPPTS 830.6303, 6317, 6320, 7000, and 7300)
47942504	Volume 5	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
47942505	Volume 6	Product Chemistry: Analysis and Certification of Product Ingredients (OPPTS 830.1700, 830.1750 and 830.1800)
47942506	Volume 7	Product Chemistry: Physical and Chemical Characteristics (OPPTS 830.6302, 6303, 6304, 6313, 7000, 7050, 7200, 7300, 7370, 7520, 7550, 7840 and 7960)
47942507	Volume 8	Acute Oral Toxicity (OPPTS 870.1100)
47942508	Volume 9	Acute Dermal Toxicity (OPPTS 870.1200)
47942509	Volume 10	Primary Eye Irritation (OPPTS 870.2400)
47942510	Volume 11	Primary Dermal Irritation (OPPTS 870.2500)
47942511	Volume 12	Skin Sensitization (OPPTS 870.2600)
47942512	Volume 13	Acute Inhalation Toxicity (OPPTS 870.1300)
47942513	Volume 14	Avian Acute Oral Toxicity (OPPTS 850.2100)
47942514	Volume 15	Avian Dietary Toxicity (OPPTS 850.2200)
47942515	Volume 16	Fish Acute Toxicity, Rainbow Trout (OPPTA 850.1075)
47942516	Volume 17	Aquatic Invertebrate Acute Toxicity, *Daphnia* (OPPTS 850.1010)
47942517	Volume 18	Compilation of Toxicology Data (OPPTS Series 870)

Company Official: Walter G. Talarek
Authorized Agent

Signature

Company Name: W. Neudorff GmbH KG

Company Contact: Walter G. Talarek (703) 759-4837
Name Phone

Memorandum

Date: 01 / 06 / 10

To: PM 91, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☑ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States Environmental Protection Agency Washington, DC 20460

EPA

[X] Registration [ ] Amendment [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702- GR	Linda Hollis	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Slugkil MP	91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Application for registration which requires PRIA service fee. The PRIA fee category is B630 because the product involves the first food use of the active ingredient and the applicant seeks to establish a tolerance exemption. This application is tied to the secondary new product applications for registration of Slugkil 2 and Slugkil 5. The total fee amount for the three applications is $18,192. The applicant may be contacted at wtalarek@verizon.net or 703-759-5548 (fax).

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [X] Other (Specify) Polypropylene
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	See label	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [X] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
W Talarek	Authorized Agent	
4. Typed Name	**5. Date**	
Walter G. Talarek	12/16/09	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Cop

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67702-GR	Linda Hollis	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Slugkil MP	91	

5. Name and Address of Applicant *(Include ZIP Code)*

W. Neudorff GmbH KG
c/o Walter G. Talarek PC 1008 Riva Ridge Drive
Great Falls, VA 22066-1620

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised product-specific and generic data matrices (EPA Forms 8570-35) in support of application for registration. The revised data matrices contain the MRID numbers assigned by EPA for the studies submitted with the application for registration. Both EPA-use and public-use copies of the forms are enclosed.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Walter G. Talarek	Authorized Agent	703-759-4837

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
W Talarek	Authorized Agent	
4. Typed Name	**5. Date**	
Walter G. Talarek	January 20, 2010	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) *Yellow - Applicant Copy

EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERL REGISTER

EPA Biopesticides and Pollution Prevention Division contact: Linda Hollis 703-308-8733

TEMPLATE:

Company Name: W. Neudorff GmbH KG

[Insert petition number]

EPA has received a pesticide petition ([ ]) from W. Neudorff GmbH KG, An der Muhle 3, 31860 Emmerthal, Germany, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.SA.C. 346a(d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for the biochemical pesticide sodium ferric EDTA.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, W. Neudorff GmbH KG has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by W. Neudorff GmbH KG, and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. W. Neudorff GmbH KG Petition Summary

[Insert petition number]

A. Product Name and Proposed Use Practices

1. Product Names: Slugkil 2 and Slugkil 5
2. Proposed Use Practices: Slugkil 2 and Slugkil 5 are molluscicides intended for application in residential outdoor, terrestrial food crop and non-food crop and greenhouse food crop and non-food crop use sites. The products will be applied around crops and plants as a barrier to slugs and snails.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*: The pesticide chemical is sodium ferric EDTA (CAS Reg. No. 15708-41-5), also known as sodium ferric ethylenediaminetetraacetic acid, and ferric sodium EDTA; Molecular Formula: $C_{10}H_{12}FeNa_2NaO_8 \cdot 3H_2O$; Molecular Weight: 421.10. The residues expected are those resulting from the dissociation of free iron and EDTA from the pesticide chemical.
2. *Magnitude of the residues at the time of harvest and method used to determine the residue*: A waiver has been requested for this data requirement based on this pesticide

chemical's (1) low toxicity and risks, (2) the metabolism of the chemical by mammals, (3) the end-use products' physical state as dry, solid pellets, (4) the chemical's use as a source of dietary iron for food fortification purposes in the US and approval by the World Health Organization for the same purpose, (5) the chemical's environmental fate, (6) the chemical's use pattern and (7) the chemical's use as a liquid fertilizer for counteracting iron deficiency in plants. Moreover, when the pesticide chemical is used as proposed, residues of toxicological concern are not expected in or on food crops.

3. *A statement of why an analytical method of detecting and measuring the levels of the pesticide residue is not needed*: This requirement is inapplicable. When the pesticide chemical is used as proposed, residues of toxicological concern are not expected in or on food crops. Therefore, if the tolerance exemption is granted, there will be no need for a practicable method for removing any amount of the residue that might occur in or on plants.

C. *Mammalian Toxicological Profile*

1. *Acute oral toxicity* (OPPTS 870.1100): Two studies were conducted, one using the technical grade of the active ingredient ("TGAI") as the test substance and the other using Slugkil 5 as the test substance. (Slugkil 5 contains 5% sodium ferric EDTA.) The TGAI was evaluated for its acute oral toxicity potential in 6 female rats when administered by gavage at a single dose of 2000 mg/kg b/w/. The test substance was tested using a stepwise procedure, each step using three female animals. The treatment was followed by an observation period of two weeks. Under the test conditions, there were no clinical signs of toxicity. No influence on animal behavior or premature mortality was noted. The macroscopic examination did not reveal any changes. The animals gained the expected body weight throughout the whole study period.

   Slugkil 5 was evaluated for its acute oral toxicity potential in female albino rats when administered as a gavage dose at a level of 5000 mg/kg. No mortality occurred during the study. There were no clinical signs of toxicity during the study. There was no effect on body weight gain. The gross necropsy conducted at termination of the study revealed no observable abnormalities. The acute oral LD_{50} was estimated to be greater than 5000 mg/kg.

2. *Acute dermal toxicity* (OPPTS 870.1200): Two studies were conducted, one using the TGAI as the test substance and the other using Slugkil 5 as the test substance. The TGAI was evaluated for its acute dermal toxicity potential in 5 male and 5 female rats. The animals were once dermally exposed to the test substance for 24 hours on the shaved intact dorsal skin at a dose of 2000 mg/kg b.w. This treatment was followed by an observation period of 2 weeks. Under the test conditions, there were no clinical signs of toxicity. No influence on animal behavior or premature mortality was noted. No skin reaction was observed. The macroscopic examination did not reveal any changes. The animals gained the expected body weight gain throughout the whole study period.

   Slugkil 5 was evaluated for it dermal toxicity potential and relative skin irritancy when a single dose moistened with 0.5 mL of deionized water/g test substance, at a

level of 5050 mg/kg, was applied to the intact skin of albino rats. No mortality occurred during the study. There were no clinical signs of toxicity at any time throughout the study. Signs of dermal irritation included erythema, eschar, focal bleeding, alopecia, discoloration and shallow fissuring. There was no effect on body weight gain, with the exception of two test animals that lost weight during the first week. The gross necropsy conducted at termination of the study revealed no observable abnormalities. The estimated LD_{50}, as indicated by the data, was determined to be greater than 5050 mg/kg.

3. *Acute inhalation toxicity* (OPPTS 870.1300): One study was conducted using the TGAI as the test substance. The TGAI was evaluated for its acute inhalation toxicity potential in 5 male and 5 female rats. The test substance was dissolved in water to a 5.7% solution as no dust aerosol could be generated. A 5.7% solution was the approximate limit of solubility. The animals were exposed to the test substance at an actual concentration of 2.75 mg/L air for 4 hours by inhalation. After completion of exposure the animals were observed for a period of 14 days. Clinical examinations were made at least once a day until all symptoms had subsided, and thereafter each working day. Body weight was measured immediately before administration and on test days 8 and 15. No mortality was observed; and there were no clinical findings. Body weight development was in the normal range.
4. *Primary eye irritation* (OPPTS 870.2400): Two studies were conducted, one using the TGAI as the test substance and the other using Slugkil 5 as the test substance. The TGAI was evaluated for its potential eye irritancy. Three male rabbits were exposed to the test substance at a dose level of 100 mg per animal in the conjunctival sacs of their right eyes. The eyes were examined 60 minutes, 24 hours, 48 hours, 72 hours, 4 days and 7 days after instillation. One of the 3 rabbits exposed to the test substance showed corneal opacity (grade 1) 24 hours to 6 days after instillation. Conjunctival redness (grade 1) was observed in animal no. one 60 minutes, in animal no. two 60 minutes to 48 hours, and in animal no. three 24 hours to 4 days after instillation. The fluorescein test performed 24 hours after instillation revealed corneal staining in animal no. 3 (up to ¼ of the surface). All observed ocular reactions were reversible during the post-exposure period.

   Slugkil 5 was evaluated for its potential eye irritancy. Three rabbits were exposed to Slugkil 5 in the conjunctival sacs of their right eyes. All three animals showed conjunctival redness (grade 1) 1 hour after instillation; and animals nos. 1 and 2 showed conjunctival redness until 24 hours after instillation. In addition, secretion was observed in all three animals 1 hour after instillation. All observed ocular reactions were reversible during the post-exposure period. No eye irritation was noted after 24 hours (animal no. 3) or 48 hours (animal nos. 1 and 2) after application of the test item.
5. *Primary dermal irritation* (OPPTS 870.2500): Two studies were conducted, one using the TGAI as the test substance and the other using Slugkil 5 as the test substance. The TGAI was evaluated for it potential skin irritancy. Three male rabbits were exposed to the test substance at a dose level of 500 mg/patch by dermal application onto the shaved, intact dorsal skin for 4 hours. The reactions of the skin were evaluated 60 minutes, 24 hours, 48 hours and 72 hours after patch removal. One of the three rabbits showed erythema (grade 1) 1 hour after patch removal.

Slugkil 5 was evaluated for its potential skin irritancy. Three rabbits were exposed dermally for 4 hours to Slugkil 5. All animals showed erythema (grade 1) 1 hour after patch removal, and animal nos. 2 and 3 showed erythema 24 hours after patch removal. All observed changes to the skin were reversible during the post-exposure period. No dermal irritation was noted after 24 hours (animal no. 1) or 48 hours (animal nos. 2 and 3) after application of the test substance.

6. *Dermal sensitization* (OPPTS 870.2600): Two studies were conducted, one using the TGAI as the test substance and the other using Slugkil 5 as the test substance.The TGAI was evaluated for its potential to cause skin sensitization. Three concentrations of the test substance (10%, 25% and 50% w/w) dissolved in acetone/olive oil (3+1, v/v) were tested in six female CBA mice per group and compared to a vehicle control group. In addition, a positive control group (30% solution v/v of α-hexyl cinnamic aldehyde in acetone/olive oil (3+1, v/v)) was employed. Open application of 25 uL of the appropriate dilution of the test item, the vehicle alone or the positive control (as appropriate) were administered to the dorsum of each ear on 3 consecutive days. On test day 4 the animals were sacrificed, and ear weight (punch biopsies), ear swelling and weight and cell count of the lymph nodes were measured. The study concluded that the TGAI at concentrations of 10, 25 or 50% (w/w) in acetone/olive (3+1, v/v) did not show any sensitizing properties in the local lymph node assay in mice.

   Slugkil 5 was evaluated for its potential to cause skin sensitization. Three concentrations of the test substance (10%, 25% and 50% w/w) dissolved in dimethylacetamide/acetone/ethanol (4+3+3, v/v/v) were tested in six female CBA mice per group and compared to a vehicle control group. In addition, a positive control group (30% solution v/v of α-hexyl cinnamic aldehyde in dimethylacetamide/acetone/ethanol (4+3+3, v/v/v)) was employed. Open application of 25 uL of the appropriate dilution of the test item, the vehicle alone or the positive control (as appropriate) were administered to the dorsum of each ear on 3 consecutive days. On test day 4 the animals were sacrificed, and ear weight (punch biopsies), ear swelling and weight and cell count of the lymph nodes were measured. The study concluded that Slugkil 5 at concentrations of 10, 25 or 50% (w/w) in dimethylacetamide/acetone/ethanol (4+3+3, v/v/v) did not show and sensitizing properties in the local lymph node assay in mice.

7. *Subchronic toxicity, immunotoxicty, teratogenicty and genotoxicity* (OPPTS 870.3100, 3250, 3465, 3550, 3700, 5100, 5300 and 5375): Waivers are requested for all applicable subchronic toxicity, immunotoxicity, teratogenicity and genotoxicity data requirements. In support of this waiver request, Neudorff is relying primarily on EPA's Biopesticides Registration Action Document on Sodium Ferric Ethylenediaminetetraacetate (PC Code 139114)(November 20, 2008) (hereinafter referred to as the "BRAD") and the compilation of toxicology studies submitted in support of Neudorff's application for registration of Slugkil MP, which includes the studies cited in EPA's BRAD (see Volume 18).

In further support of it waiver requests, Neudorff notes that iron is an essential element for nutrition and is used in nutritional supplements. Elemental iron is listed as Generally Recognized as Safe ("GRAS") by the Food and Drug Administration ("FDA") (21 CFR § 184.1375). Further, FDA has promulgated a direct food additive regulation for disodium EDTA (21 CFR § 172.135) and a regulation approving the use of up to 240 ppm disodium EDTA as an additive in finished animal feed (21 CFR § 573.360). Moreover, EPA has promulgated a tolerance exemption for tetrasodium EDTA when used in pesticide formulations as an inert (and occasionally active) ingredient applied to growing crops or to raw agricultural commodities after harvest (40 CFR 180.910). In Canada, sodium ferric EDTA falls under the category of a mineral nutrient as per the definition in Part D, Division 2 of the Food and Drug Regulations (PRD2007-13, 2007).

Further, ferric sodium EDTA is used as a source of dietary iron for food fortification purposes in the US and is approved for this use by the World Health Organization. The Joint FAO/WHO Expert Committee of Food Additives examined the existing data on iron EDTA and found no objection to its use at a level of 2.5 mg/kg of body weight per day (WHO/NHD/01.3, 2001).

90-day oral toxicity (one species) (OPPTS 870.3100): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "[n]o references for feeding studies using Sodium Ferric EDTA were located in the published literature. Rats fed low mineral diets with or without added calcium disodium EDTA for four months had reduced weight gain, but their general condition was comparable to that of controls (Yang, 1964). Rats fed 1%, 5%, or 10% disodium salt of EDTA for 90 days had significantly lower food consumption and weight gain than controls (Wynn et al. 1970). Hematology was comparable among all groups, except that prothrombin time was increased in the 10% group. The only significant necropsy finding was pale livers in the 10% group."

"Mice fed 3750 or 7500 ppm trisodium EDTA for 103 weeks had no treatment-related clinical signs, and gross and microscopic pathology were unremarkable (National Cancer Institute, 1977). A companion study conducted by NCI using rats produced the same results (National Cancer Institute, 1977). In a 12-month feeding study using dogs, Oser et al. (1963) found no significant changes in hematology or urinalysis parameters, and no abnormal gross or microscopic findings in groups receiving up to 250 mg/kg/ body weight/day of calcium disodium EDTA." *Id.* at 8 of 17.

90-day dermal toxicity – rat (OPPTS 870.3250): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "[t]he end product containing Sodium Ferric EDTA is a pellet that does not produce any dust and is applied directly to the ground. Therefore, it is unlikely that there will be any dermal exposure when the product is applied according to the label directions. Furthermore, Sodium Ferric EDTA was demonstrated to be practically non-toxic (Toxicity

Category IV) to rats in an acute dermal toxicity guideline study (MRID 45848104)." *Id.* at 8 of 17.

Apropos of the above determination, the two end-products for which Neudorff is seeking registrations, i.e., Slugkil 5 and Slugkil 2, and for which Slugkil MP is the manufacturing-use product, are pellets that do not produce any dust and are applied directly to the ground; and, the acute dermal toxicity studies submitted with the applications for registration of Slugkil MP and Slugkil 5 confirm the practical non-toxicity of the technical grade of the active ingredient.

90-day inhalation toxicity – rat (OPPTS 870.3465): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "[s]ince the end product is a pellet that does not produce any dust and is applied directly to the ground, it is unlikely that there will be any inhalation exposure when the product is applied according to label directions. Furthermore, Sodium Ferric EDTA was demonstrated to be practically non-toxic (Toxicity Category IV) to rats in an acute inhalation guideline study (MRID 45848105)" *Id.* at 8 and 9 of 17.

Apropos of the above determination, the two end-products for which Neudorff is seeking registrations, i.e., Slugkil 5 and Slugkil 2, and for which Slugkil MP is the manufacturing-use product, are pellets that do not produce any dust and are applied directly to the ground; and, the acute inhalation toxicity study submitted with the application for registration of Slugkil MP confirms the practical non-toxicity of the technical grade of the active ingredient.

Immunotoxicity (OPPTS 870.3550): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "[n]o literature was located suggesting that Sodium Ferric EDTA impacts the immune system. FDA has approved calcium disodium EDTA and disodium EDTA as food additives, and these materials are added to a wide range of processed foods at levels of 200 to 500 ppm. Based on the use of EDTA and iron supplements as food ingredients, there do not appear to be any concerns regarding immune system safety issues." *Id.* at 9 of 17.

Prenatal development (OPPTS 870.3700): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "[t]he teratogenic potential of disodium EDTA has been investigated (Swenerton and Hurley, 1971; Gasset and Akaboshi, 1977; Kimmel, 1977) with variable results. The differences in toxicity shown in the scientific literature probably relate to several factors, such as absorption differences, stress associated with the administration of treatments, different species and strain susceptibility, and interaction with metals (Kimmel, 1977). Since it has been shown that EDTA may chelate zinc (Swenterton and Hurley, 1971), the exchange of iron for zinc is the predominant reaction of concern during pregnancy because of the potential effect of disodium EDTA on zinc balance, and the high sensitivity of the developing embryo to zinc deficiency (Hurley and Swenerton, 1966; Swenerton and Hurley, 1971; Kimmel, 1975; and Kimmel and Slaoan, 1975).

Effects of EDTA on zinc balance depend on the EDTA:zinc ratio, and the dietary dose range of 2.5 mg EDTA/kg bw/day recommended by the FAO/WHO Expert Committe on Food Additives (JECFA, 1974) would not be expected to have detrimental effects on zinc balance. Overall, many of the results found in the scientific literature, including Schardein et al. (1981), indicated little or no teratogenic effect of disodium EDTA in rats and rabbits. Based on the submitted data, the active ingredient is not likely to be teratogenic." *Id.* at 9 of 17.

Bacterial reverse mutation test (OPPTS 870.5100): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "Sodium Ferric EDTA with and without S9 activation was found to be mutagenic in a L5178Y tk+/tk- mouse lymphoma assay, but not mutagenic with or without S9 activation in an Ames *Salmonella* assay (Dunkel et al., 1999). Heimbach et al. (2000) concluded that the positive results seen for sodium ferric EDTA in the mouse lymphoma assay conducted by Dunkel et al. (1999) were most likely due to the sensitivity of L5178Y cells to the abnormally high iron concentrations. No other references suggesting that Ferric iron has mutagenic potential were found in the literature."

"In a L5178Y tk+/tk- mouse lymphoma cell forward mutation assay using trisodium EDTA (McGregor et al., 1988), no mutagenicity was seen with or without added S9. In another study, Heindorff et al. (1983) reported that EDTA inhibits DNA synthesis and repair, and produces a low degree of chromosomal damage and gene mutations in vitro. However, FDA scientists (Lerner et al., 1986) concluded that these events were spurious indicators of genotoxic potential, likely caused by chelation of cations that are important as enzymatic cofactors involved in DNA synthesis in the cell. According to Heindorff et al. (1983) 'the mechanism(s) by which EDTA causes genetic effects is poorly understood. Most data support the idea that EDTA itself does not induce genotoxic effects. Such effects are probably due to the cation deficiency induced by the sequestering agent. Consequently, the ultimate cause of genotoxic effects would consist in variation of the cation level.'" *Id.* at 9 of 17.

In vitro mammalian cell assay (OPPTS 870.5300): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "Sodium Ferric EDTA with and without S9 activation was found to be mutagenic in a L5178Y tk+/tk- mouse lymphoma assay, but not mutagenic with or without S9 activation in an Ames *Salmonella* assay (Dunkel et al., 1999). Heimbach et al. (2000) concluded that the positive results seen for sodium ferric EDTA in the mouse lymphoma assay conducted by Dunkel et al. (1999) were most likely due to the sensitivity of L5178Y cells to the abnormally high iron concentrations. No other references suggesting that Ferric iron has mutagenic potential were found in the literature."

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synthesis and repair, and produces a low degree of chromosomal damage and gene mutations in vitro. However, FDA scientists (Lerner et al., 1986) concluded that these events were spurious indicators of genotoxic potential, likely caused by chelation of cations that are important as enzymatic cofactors involved in DNA synthesis in the cell. According to Heindorff et al. (1983) 'the mechanism(s) by which EDTA causes genetic effects is poorly understood. Most data support the idea that EDTA itself does not induce genotoxic effects. Such effects are probably due to the cation deficiency induced by the sequestering agent. Consequently, the ultimate cause of genotoxic effects would consist in variation of the cation level.'" *Id.* at 9 of 17.

In vitro mammalian cell assay (OPPTS 870.5375): A waiver is requested for this data requirement. In waiving this data requirement, the BRAD stated "Sodium Ferric EDTA with and without S9 activation was found to be mutagenic in a L5178Y tk+/tk- mouse lymphoma assay, but not mutagenic with or without S9 activation in an Ames *Salmonella* assay (Dunkel et al., 1999). Heimbach et al. (2000) concluded that the positive results seen for sodium ferric EDTA in the mouse lymphoma assay conducted by Dunkel et al. (1999) were most likely due to the sensitivity of L5178Y cells to the abnormally high iron concentrations. No other references suggesting that Ferric iron has mutagenic potential were found in the literature."

"In a L5178Y tk+/tk- mouse lymphoma cell forward mutation assay using trisodium EDTA (McGregor et al., 1988), no mutagenicity was seen with or without added S9. In another study, Heindorff et al. (1983) reported that EDTA inhibits DNA synthesis and repair, and produces a low degree of chromosomal damage and gene mutations in vitro. However, FDA scientists (Lerner et al., 1986) concluded that these events were spurious indicators of genotoxic potential, likely caused by chelation of cations that are important as enzymatic cofactors involved in DNA synthesis in the cell. According to Heindorff et al. (1983) 'the mechanism(s) by which EDTA causes genetic effects is poorly understood. Most data support the idea that EDTA itself does not induce genotoxic effects. Such effects are probably due to the cation deficiency induced by the sequestering agent. Consequently, the ultimate cause of genotoxic effects would consist in variation of the cation level.'" *Id.* at 9 of 17.

D. Aggregate Exposure

1. Dietary exposure

i. Food. Sodium ferric EDTA is intended for application to soil surfaces around agricultural crops, plants, turf, ornamentals, and home gardens to control slugs and snails. The pesticide chemical is applied as a solid pellet; and if used as directed, is not likely to result in residues on crops or plants. Therefore, dietary exposure from use of ferric sodium EDTA, as proposed, is expected to be minimal.

Moreover, sodium ferric EDTA is used in agriculture as a micronutrient and also as a way of fortifying foods to prevent anemia and iron deficiencies in developing countries. The dietary residues from the Slugkil 2 and Slugkil 5 products would be the same as those resulting from the dissociation of free iron and EDTA from sodium ferric EDTA used as a micronutrient fertilizer treatment for iron-deficient soils and plants. Many of these micronutrient fertilizers contain higher concentrations of iron and higher application rates than those proposed for the Slugkil 2 and Slugkil 5 products. Further, in a published safety assessment on ferric sodium EDTA for FDA GRAS evaluation, the conclusion was the ingredient is regarded as safe for use in foods to increase iron bioavailability in human diets (Heimbach *et al.* 2000).

The components of ferric sodium EDTA are approved as direct food additives by FDA. Iron is an essential element for nutrition and is used in nutritional supplements. Elemental iron is listed as Generally Recognized as Safe ("GRAS") by the Food and Drug Administration ("FDA") (21 CFR § 184.1375). Further, FDA has promulgated a direct food additive regulation for disodium EDTA (21 CFR § 172.135) and a regulation approving the use of up to 240 ppm disodium EDTA as an additive in finished animal feed (21 CFR § 573.360).

EPA has promulgated a tolerance exemption for tetrasodium EDTA when used in pesticide formulations as an inert (and occasionally active) ingredient applied to growing crops or to raw agricultural commodities after harvest (40 CFR 180.910). In Canada, sodium ferric EDTA falls under the category of a mineral nutrient as per the definition in Part D, Division 2 of the Food and Drug Regulations (PRD2007-13, 2007).

Dietary exposures that might occur would not be expected to pose any risks of concern. Results of testing demonstrate that sodium ferric EDTA is of low acute toxicity. Aside from being categorized as mildly irritating to eyes, the pesticide chemical is not genotoxic, carcinogenic or considered to have any significant effect with respect to short-term chronic toxicity and reproductive toxicity. Based on short and long-term clinical observations and on the structure and associated functional groups of sodium ferric EDTA, it is not expected that the pesticide chemical will be neurotoxic.

ii. *Drinking water.* Ferric sodium EDTA is intended for application to soil surfaces around agricultural crops, turf, ornamentals, and home gardens to control slugs and snails. The pesticide chemical is not applied directly to water or to areas where surface water is present, and if used as directed, is not likely to accumulate in drinking water. Therefore, no significant exposure via drinking water is expected when the pesticide chemical is used according to the directions for use on the Slugkil 2 and Slugkil 5 labels. In the unlikely event that exposure via

drinking water does occur, the health risk would be expected to be minimal because of the low acute oral and acute dermal toxicity of the pesticide chemical.

2. *Non-dietary exposure.* The potential for non-dietary exposure to the general population is limited. The Slugkil products, which contain sodium ferric EDTA, are pellets that are applied to soil surfaces around agricultural crops, plants, turf, ornamentals, and home gardens to control slugs and snails. Occupational exposure is expected to be short term and predominantly by the dermal route when pellets are handled during application. This exposure is not expected to be significant based on the physical properties of the pellets and the mitigating statements on the Slugkil products' labels. Similarly, exposure to persons in residential, school and day care areas is not expected to be significant because the Slugkil products are pelleted baits applied directly to soil, and when they are used according to label directions. A public literature review of toxicological and exposure data (Heimbach et al., 2000) concluded that sodium ferric EDTA may be generally regarded as safe. Should accidental exposure occur, the health risk is expected to be minimal, based on the pesticide chemical's low acute, dermal and inhalation toxicities.

E. Cumulative Effects.

When the Slugkil products are used as proposed, residues of sodium ferric EDTA will not reach levels that are of toxicological concern. Because of the pesticide chemical's low toxicity, cumulative effects with other substances that share a common mechanism of toxicity are not expected.

F. Safety Determination

1. *U.S. population.* Significant human exposure of the U.S. population to sodium ferric EDTA is unlikely when the Slugkil end-use products are used according to their labels' directions. The end-use products are pelletized baits that are applied directly to soil. When the products are used as proposed, residues that are of toxicological concern should not occur, and therefore there is a reasonable certainty that no harm to the U.S. population will result from exposure to the pesticide chemical from the proposed uses. However, should accidental exposure occur, the health risk is expected to be minimal based on the low acute oral, dermal and inhalation toxicity of sodium ferric EDTA. Further, a public literature review of the toxicological and exposure data on sodium ferric EDTA concluded that the chemical may be generally regarded as safe (Heimbach et al., 2000). Moreover, the components of ferric sodium EDTA are approved as direct food additives by FDA; and sodium ferric EDTA is used in agriculture as a micronutrient and also as a way of fortifying foods to prevent anemia and iron deficiencies in developing countries. (WHO/NHD/01.3, 2001).

2. *Infants and children.* Significant human exposure to sodium ferric EDTA is unlikely in residential, school and day care areas when the Slugkil end-use products are used according to their labels' directions. The end-use products are pelletized baits that are applied directly to soil. When the products are used as proposed, residues that are of toxicological concern should not occur, and therefore there is a reasonable certainty that no harm to infants and children will result from exposure to the chemical from the proposed uses. However, should accidental exposure occur, the health risk is expected to be minimal based on the low acute oral, dermal and inhalation toxicity of sodium ferric EDTA. A public literature review of the toxicological and exposure data on sodium ferric EDTA concluded that the chemical may be generally regarded as safe (Heimbach et al., 2000). Moreover, the components of ferric sodium EDTA are approved as direct food additives by FDA; and sodium ferric EDTA is used in agriculture as a micronutrient and also as a way of fortifying foods to prevent anemia and iron deficiencies in developing countries. (WHO/NHD/01.3, 2001).

G. Effects on the Immune and Endocrine Systems

No literature was located suggesting that sodium ferric EDTA impacts the immune system. FDA has approved calcium disodium EDTA and disodium EDTA as food additives, and these materials are added to a wide range of processed foods at levels of 200 to 500 ppm. Based on the use of EDTA and iron supplements as food ingredients, there do not appear to be any concerns regarding immune system safety issues.

Based on the weight of the evidence of available data, no endocrine-related effects have been identified for sodium ferric EDTA and none are expected since it does not share any structural similarity to any known endocrine disruptor.

H. Existing Tolerances

There are no tolerances or tolerance exemptions for sodium ferric EDTA.

I. International Tolerances

Neudorff is not aware of any country requiring a tolerance for sodium ferric EDTA, nor have any MRLs for any crop been established by the Codex Alimentarius Commission. Moreover, Canada's Pest Management Regulatory Agency has determined that MCLs are not needed for the fruit and vegetable uses of this active ingredient (RD2008-04).

21-Day Screen Completed by Contractor

21-Day Expires on 1-12-10

Jacket # 67702-6R
MRID# 479425

Content Screen: Recommended to Pass/Fail

86-5 Review: Passed/Failed/NA

Transfer This Jacket to:

LINDA HOLLIS

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 12-22-09

Experts In-Processing Signature: MF HARRINGTON Date 12-30-09 Fee Paid: Yes ✓

Division management contacted on issues No_____Yes_____Date_____

EPA Reg. Number: 67702-GR	EPA Receipt Date: 12-22-09

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)	X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) — yes: X; no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)	X		
	Certificate and data matrix consistent	X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes: ; no:			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)	X		
	a) Selective Method (Fee category experts use) — yes: X; no:			
	b) Cite-All (Fee category experts use) — yes: ; no:			
	c) Applicant owns all data (Fee category experts use) — yes: ; no:			
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)	X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Inerts approved
MP 12/31/09.

Studies had illegible pages & confidential marking issues. contacted registrant 1/4/10. Registrant sent in pages 1/4/10
MP

MRID 479425

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 30, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-425379
EPA File Symbol or Registration Number: 67702-GR
Product Name: SLUGKIL MP
EPA Receipt Date: 22-Dec-2009
EPA Company Number: 67702
Company Name: W. NEUDORFF GMBH KG

WALTER G TALAREK
W. NEUDORFF GMBH KG
POSTFACH 1209
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B630

NEW USE;FIRST FOOD USE;MICROBIAL/BIOCHEMICAL WITH EXEMPTION;

No additional payment is due at this time. We will process a refund of your $7,167 overpayment as soon as is practicable.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{864588` ~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ◉ BPPD
- ○ RD

Risk Mgr. 91

Receipt No. S-	864588
EPA File Symbol/Reg. No.	67702-GR
Pin-Punch Date:	12/22/2009

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B630

Granted: B630

Amount Due: $ 11,025

Parent/Child Decisions:

2 EP applic & 1 Tol Ex Petition are affiliated w/ this application

67702-GE

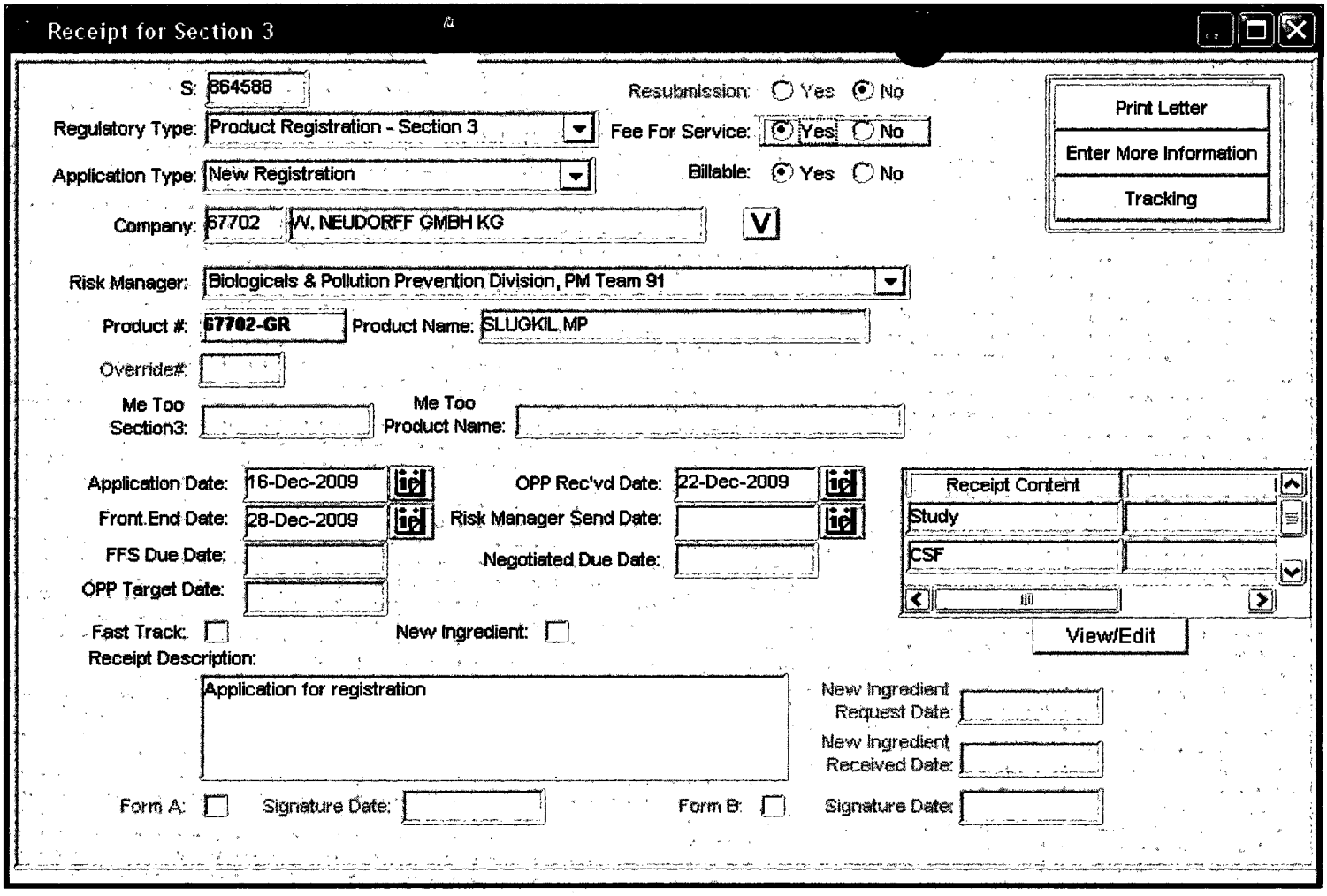
67702-GG

9F7668

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Andrew Bryceland Date: 12/29/09

Remarks:


Receipt for Section 3
S: 864588
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 67702 W. NEUDORFF GMBH KG
Print Letter
Enter More Information
Tracking
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91
Product #: 67702-GR
Product Name: SLUGKIL MP
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 16-Dec-2009
OPP Rec'vd Date: 22-Dec-2009
Front End Date: 28-Dec-2009
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Application for registration
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

FEE FOR SERVICE

WALTER G TALAREK PC
1008 RIVA RIDGE DR
GREAT FALLS, VA 22066-1620
PH. 703-759-4837

5325
65-270/550

DATE 12/16/09

PAY TO THE ORDER OF ENVIRONMENTAL PROTECTION AGENCY $ 18,192.00

EIGHTEEN THOUSAND ONE HUNDRED NINETY TWO DOLLARS

SUNTRUST

FOR PRIA APPLICATION FEES
W. NEUDORFF GMBH KG - CO. NO. 67702

W G Talarek

"005325" [redacted]

Commercial/financial information may be entitled to confidential treatment

LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

December 16, 2009

DELIVERED BY COURIER
Linda Hollis, PM 91
Biopesticides and Pollution Prevention Division
U.S. Environmental Protection Agency
c/o Document Processing Desk (APPL)(REGFEE)
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Applications for Registration
Slugkil MP; Slugkil 5; and Slugkil 2
W. Neudorff GmbH KG

Dear Ms. Hollis:

On behalf of W. Neudorff GmbH KG ("Neudorff"), I am submitting three (3) applications for registration of products containing sodium ferric EDTA (CAS Reg. No. 15708-41-5) as the sole active ingredient. The first product is Slugkil MP, which is a manufacturing-use product used to formulate the second and third products, whose brand names are Slugkil 2 and Slugkil 5. These latter two products are end-use molluscicidal products intended for home and garden, commercial and agriculture uses as a protective barrier around vegetables, fruits, berries, herbs, field crops, outdoor ornamentals, greenhouses, and on lawns, commercial turf, sod, golf courses, and certain non-crop barrier areas. The two end-use products are applied by hand or standard broadcast or granular spreaders. The end-use products contain the active ingredient at 2% and 5%, respectively.

These applications are primary and secondary new product applications to which PRIA fees apply. All three applications rely on the generic data that are being submitted with the application for registration of Slugkil MP, which is the primary application. In addition, acute toxicity data is being submitted with the application for registration of Slugkil 5. Neudorff submits that the applicable PRIA fee categories for the Slugkil MP, Slugkil 2 and Slugkil 5 applications are B630, B630.1 and B630.2, respectively, because the applications concern the first food uses of an old active ingredient and a petition to establish a tolerance exemption is being submitted. As such, Neudorff believes that the applicable PRIA fee is $18,192, a check for which has been sent today to EPA's Washington Finance Center in St. Louis, MO.

Neudorff is using the selective method to address both the generic and product-specific data requirements applicable to the registrations of Slugkil MP, Slugkil 2 and Slugkil 5. Neudorff is submitting data or data waiver requests to fulfill each of the data requirements applicable to the registrations of

the three products. As stated above, the generic data are being submitted with the application for registration of Slugkil MP, and the applications for registration of Slugkil 2 and Slugkil 5 cite these data. The application for registration of Slugkil MP contains product-specific product chemistry and generic acute toxicology data that is being used through waiver (bridging) requests to address the product-specific acute toxicology data requirements. The application for registration of Slugkil 5 contains product-specific product chemistry and acute toxicology data. The application for registration of Slugkil 2 contains product-specific product chemistry data. The acute toxicology data requirements applicable to the registration of Slugkil 2 are being addressed by citing the acute toxicology data being submitted with the Slugkil 5 application for registration and requesting waivers (bridging).

The data requirements for which waivers are being requested are addressed in the document titled "Correspondence Document: Explanations and Waiver Requests" that is being submitted with each application. Scientific rationales for the waiver requests are provided in this document. The scientific rationales for the generic data requirements waiver requests, for the most part, have been taken from EPA's "Biopesticides Registration Action Document [on] Sodium Ferric Ethylenediaminetetraacetate (PC Code 139114)" (November 20, 2008).

Because the applications for registration of Slugkil 2 and Slugkil 5 involve food crop uses, Neudorff is submitting a petition for an exemption from the requirement for a tolerance. Two copies of the petition are being submitted separately to EPA's Document Processing Desk. One copy of the petition is being submitted with each application for registration of Slugkil MP, Slugkil 2 and Slugkil 5. Similarly, copies of Neudorff's summary of the information, data and arguments in support of its petition, i.e., a completed template titled "EPA Biopesticides and Pollution Prevention Division Company Notice of Filing for Pesticide Petitions Published in the Federal Register", are being submitted to EPA's Document Processing Desk with the petition and with the applications for registration of Slugkil MP, Slugkil 2 and Slugkil 5. Both hard copies and electronic copies of the petition summary are being submitted to the Document Processing Desk with the petition and with the three applications for registration.

When you review the studies being submitted with the applications for registration of Slugkil 2 and Slugkil 5, please note that the test substance NEU1182 is the code name for Slugkil 5 and the test substance NEU1183 is the code name for Slugkil 2.

Five (5) copies of each product's label are enclosed. When you review the Slugkil 2 and Slugkil 5 applications, please note these products' labels are master labels that are divided into two sub-labels: one sub-label is for the home and garden use; and the other sub-label is for the commercial and agriculture uses.

If you have any questions about these applications for registration, please feel free to call me.

Sincerely yours,

Walter G. Talarek
Authorized Agent

Enclosures – Applications for Registration (3)

TRANSMITTAL DOCUMENT

1. Name and address of submitter

W. Neudorff GmbH KG
c/o Walter G. Talarek, PC
1008 Riva Ridge Drive
Great Falls, VA 22066-1620

2. Regulatory action in support of which this package is submitted

Application for registration of Slugkil MP.

3. Transmittal date

December 16, 2009

4. List of submitted studies

Volume 1	Administrative Materials
Volume 2	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
Volume 3	Product Chemistry: Analysis and Certification of Product Ingredients (OPPTS 830.1700, 830.1750 and 830.1800)
Volume 4	Product Chemistry: Physical and Chemical Characteristics (OPPTS 830.6303, 6317, 6320, 7000, and 7300)
Volume 5	Product Chemistry: Product Identity and Composition (OPPTS 880.1100, 880.1200 and 880.1400)
Volume 6	Product Chemistry: Analysis and Certification of Product Ingredients (OPPTS 830.1700, 830.1750 and 830.1800)
Volume 7	Product Chemistry: Physical and Chemical Characteristics (OPPTS 830.6302, 6303, 6304, 6313, 7000, 7050, 7200, 7300, 7370, 7520, 7550, 7840 and 7960)
Volume 8	Acute Oral Toxicity (OPPTS 870.1100)
Volume 9	Acute Dermal Toxicity (OPPTS 870.1200)
Volume 10	Primary Eye Irritation (OPPTS 870.2400)
Volume 11	Primary Dermal Irritation (OPPTS 870.2500)
Volume 12	Skin Sensitization (OPPTS 870.2600)
Volume 13	Acute Inhalation Toxicity (OPPTS 870.1300)
Volume 14	Avian Acute Oral Toxicity (OPPTS 850.2100)
Volume 15	Avian Dietary Toxicity (OPPTS 850.2200)
Volume 16	Fish Acute Toxicity, Rainbow Trout (OPPTA 850.1075)
Volume 17	Aquatic Invertebrate Acute Toxicity, *Daphnia* (OPPTS 850.1010)
Volume 18	Compilation of Toxicology Data (OPPTS Series 870)

Volume 19 Compilation of Environmental Fate Data (OPPTS Series 835)

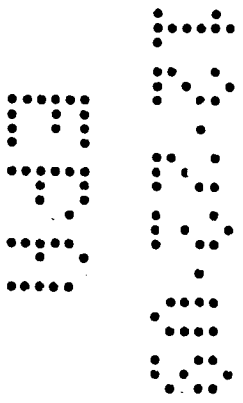
Company Official: Walter G. Talarek
Authorized Agent

Signature

Company Name: W. Neudorff GmbH KG

Company Contact: Walter G. Talarek (703) 759-4837
Name Phone

TABLE OF CONTENTS



LAW OFFICES OF
WALTER G. TALAREK, P.C.
1008 RIVA RIDGE DRIVE
GREAT FALLS, VA 22066-1620

PHONE: 703-759-4837
FAX: 703-759-5548
E-MAIL: WTALAREK@VERIZON.NET

December 16, 2009

DELIVERED BY COURIER
Office of Pesticide Programs (PETN)
Registration Division (7505C)
U. S. Environmental Protection Agency
c/o Document Processing Desk
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Petition for Exemption from Requirement for a Tolerance for Sodium Ferric EDTA

Dear Madam or Sir:

On behalf of W. Neudorff GmbH KG ("Neudorff"), and pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), I am submitting the enclosed petition for an exemption from the requirement for a tolerance for the pesticide sodium ferric EDTA (CAS Reg. No. 15708-41-5). Neudorff is submitting concurrently with this petition applications for registration of two end-use products containing sodium ferric EDTA as the active ingredient for use on food crops. These products' brand names are Slugkil, 2 and Slugkil 5, which contain the active ingredient at 2% and 5%, respectively. Neudorff also is submitting concurrently with this petition and the two applications for registration of end-use products, an application for registration of a manufacturing-use product containing sodium ferric EDTA with the brand name of Slugkil MP.

Attached hereto in duplicate and constituting parts of this petition are the following:

A. The name, chemical identity, and composition of the pesticide chemical. See Attachment A;
B. The recommended amount, frequency, and time of application of the pesticide chemical. See Attachment B;
C. Reports of tests and investigations made with respect to the safety of the pesticide chemical. See Attachment C;
D. Reports of tests and investigations made with respect to the nature and amount of pesticide chemical residue that is likely to remain, including a description of the analytical methods used. See Attachment D;
E. Proposed exemption from the requirement for a tolerance. See Attachment E; and
F. Practicable methods for removing residue that exceeds any proposed tolerance. See Attachment F;
G. Practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food or a statement why such method is not needed. See Attachment G;
H. For a tolerance relating to processed food, reports of investigations conducted using the processing methods use to produce that food. See Attachment H;

I. Such information as the Administrator may require to make the determination under FFDCA section 408(b)(2)(C). See Attachment I;
J. Such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen or other endocrine effects. See Attachment J;
K. Information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue; See Attachment K;
L. Information concerning any maximum residue level established by the Codex Alimentarius Commission for the pesticide chemical residue addressed in the petition; See Attachment L;
M. Such other data and information as the Administrator requires by regulation to support the petition. See Attachment M.
N. Reasonable grounds in support of the petition. See Attachment N.

Neudorff's mailing address to which a notice of objection under FFDCA section 408(g)(2) may be sent is c/o Walter G. Talarek PC, 1008 Riva Ridge Drive Great Falls, VA 22066-1620.

An informative summary of the petition and the data, information, and arguments submitted or cited in support of the petition is enclosed. Both paper and electronic copies of this summary are enclosed. Neudorff agrees that such summary or any information it contains may be published as part of the notice of filing of the petition to be published under FFDCA section 408(d)(3) as part of a proposed or final regulation issued under FFDCA section 408.

The pesticide registration service fee required under section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act for a new product for the first food use of an active ingredient and for which a tolerance exemption has been requested, i.e., PRIA fee category B630, has been sent to EPA's Washington Finance Center address in St. Louis, MO.

If you have any questions concerning this petition, please feel free to contact me.

Sincerely yours,

Walter G. Talarek
Authorized Agent

Form Approved OMB Nos. 2070-[illegible]; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
W. Neudorff GmbH KG 1008 Riva Ridge Drive Great Falls, VA 22066-1620	67702-
Active Ingredient(s) and/or representative test compound(s) Sodium Ferric EDTA	Date December 16, 2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non-food Crop; Greenhouse Food and Non-food Crop; Residential Outdoor	Product Name Slugkil MP

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Walter G. Talarek	12/16/09	Walter G. Talarek/Authorized Agent

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

12-22-09

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DATA MATRIX (Generic)

Date: December 16, 2009	EPA Reg. No./File Symbol: 67702-	Page 1 of 4
Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	Product: Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
880.1100	Product identity and composition		67702	OWN	
880.1200	Description of materials used to produce product		67702	OWN	
880.1200	Description of production process		67702	OWN	
880.1400	Discussion of formation of impurities		67702	OWN	
830.1700	Preliminary analysis		67702	OWN	
830.1750	Certified limits		67702	OWN	
830.1800	Enforcement analytical method		67702	OWN	
830.6302	Color		67702	OWN	
830.6303	Physical state		67702	OWN	
830.6304	Odor		67702	OWN	
830.6313	Stability		67702	OWN	
830.7000	pH		67702	OWN	
830.7050	UV/visible light absorption		67702	OWN	
830.7200	Melting point/melting range		67702	OWN	
830.7220	Boiling point/boiling range				N.A.
830.7300	Density, bulk density or specific gravity		67702	OWN	
830.7370	Dissociation constant		67702	OWN	

Signature	Name and Title Walter G. Talarek Authorized Agent	Date 12/16/09

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DATA MATRIX (Generic)

Date: December 16, 2009	EPA Reg. No./File Symbol: 67702-	Page 2 of 4
Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 Emmerthal, Germany	Product: Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7520	Particle size, fiber length, and diameter		67702	OWN	
830.7550	Partition coefficient		67702	OWN	
830.7840	Water solubility		67702	OWN	
830.7960	Vapor pressure		67702	OWN	
835	Compilation of environmental fate studies		67702	OWN	
850.1010	Aquatic invertebrate acute toxicity, freshwater		67702	OWN	
850.1075	Fish acute toxicity, freshwater		67702	OWN	
850.2100	Avian acute oral toxicity		67702	OWN	
850.2200	Avian dietary toxicity		67702	OWN	
850.4100	Terrestrial plant toxicity, seedling emergence				Waiver Request
850.4150	Terrestrial plant toxicity, vegetative vigor				Waiver Request
880.4350	Nontarget insect testing	47233004	67702	OWN	Waiver Request
860.1100	Chemical identity		67702	OWN	
860.1200	Directions for use		67702	OWN	
860.1300	Nature of the residue in plants				Waiver Request
860.1340	Residue analytical method				Waiver Request
860.1500	Crop field trials				Waiver Request
860.1540	Anticipated residues				Waiver Request

Signature	Name and Title Walter G. Talarek Authorized Agent	Date 12/16/09

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DATA MATRIX (Generic)

Date: December 16, 2009	EPA Reg. No./File Symbol: 67702-	Page 3 of 4
Applicant's/Registrant's Name & Address: W. Neudorff GmbH KG, An der Muhle 3, 31860 Emmerthal, Germany	Product: Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1550	Proposed tolerances		67702		See petition for tol. exemption
860.1560	Reasonable grounds in support of petition		67702		See petition for tol. exemption
860.1650	Submittal of analytical standards				Waiver Request
870	Compilation of toxicology studies		67702	OWN	
870.1100	Acute oral toxicity		67702	OWN	
870.1200	Acute dermal toxicity		67702	OWN	
870.1300	Acute inhalation toxicity		67702	OWN	
870.2400	Primary eye irritation		67702	OWN	
870.2500	Primary dermal irritation		67702	OWN	
870.2600	Skin sensitization		67702	OWN	
None	Hypersensitivity incidents				No Data
870.3100	90-day oral (one species)				Waiver Request
870.3250	90-day dermal - rat				Waiver Request
870.3465	90-day inhalation - rat				Waiver Request
870.3550	Immunotoxicity				Waiver Request
870.3700	Prenatal development				Waiver Request

Signature	Name and Title: Walter G. Talarek, Authorized Agent	Date: 12/16/09

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DATA MATRIX (Generic)

Date: December 16, 2009

EPA Reg. No./File Symbol: 67702-

Applicant's/Registrant's Name & Address W. Neudorff GmbH KG
An der Muhle 3
31860 Emmerthal, Germany

Product: Slugkil MP

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Bacterial reverse mutation test				Waiver Request
870.5300	In vitro mammalian cell assay				Waiver Request
870.5375	In vitro mammalian cell assay				Waiver Request
870.5385	In vivo mammalian cytogenetics				N.A.
870.5895	In vivo mammalian cytogenetics				N.A.
875.1100	Dermal outdoor exposure				N.A.
875.1200	Dermal indoor exposure				N.A.
875.1300	Inhalation outdoor exposure				N.A.
875.1400	Inhalation indoor exposure				N.A.
875.1500	Biological monitoring				N.A.
880.3800	Immune response				N.A.
870.3800	Reproduction and fertility effects				N.A.
870.4100	Chronic oral – rodent and nonrodent				N.A.
870.4200	Carcinogenicity – two species				N.A.
870.5380	Mammalian spermatogonial chromosome aberration test				N.A.
870.7200	Companion animal safety				N.A.

Signature W G Talarek

Name and Title Walter G. Talarek
Authorized Agent

Date 12/16/09

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DATA MATRIX (Generic)

Date: December 16, 2009	**EPA Reg. No./File Symbol:** 67702-	**Page** 1 of 4
Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	**Product:** Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
					N.A.
			67702	OWN	
			67702	OWN	

Signature Walter G. Talarek	**Name and Title** Walter G. Talarek Authorized Agent	**Date** 12/16/09

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DATA MATRIX (Generic)

Date: December 16, 2009	EPA Reg. No./File Symbol: 67702-	Page 2 of 4
Applicant's/Registrant's Name & Address: W. Neudorff GmbH KG, An der Muhle 3, Emmerthal, Germany	Product: Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
					Waiver Request
					Waiver Request
			67702	OWN	Waiver Request
			67702	OWN	
			67702	OWN	
					Waiver Request
					Waiver Request
					Waiver Request
					Waiver Request

Signature	Name and Title: Walter G. Talarek, Authorized Agent	Date: 12/16/09

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DATA MATRIX (Generic)

Date: December 16, 2009	EPA Reg. No./File Symbol: 67702-	Page 3 of 4
Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	Product: Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			67702		See petition for tol. exemption
			67702		See petition for tol. exemption
					Waiver Request
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
					No Data
					Waiver Request
					Waiver Request
					Waiver Request
					Waiver Request
					Waiver Request

Name and Title Walter G. Talarek
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Date 12/16/09

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DATA MATRIX (Generic)

Date: December 16, 2009	**EPA Reg. No./File Symbol:** 67702-	**Page** 4 of 4
Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	**Product:** Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					Waiver Request
					Waiver Request
					Waiver Request
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.
					N.A.

Signature W G Talarek	**Name and Title** Walter G. Talarek Authorized Agent	**Date** 12/16/09

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DATA MATRIX (Product-Specific)

Date: December 16, 2009	**EPA Reg. No./File Symbol:** 67702-	**Page 1 of 2**
Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	**Product:** Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
880.1100	Product identity and composition		67702	OWN	
880.1200	Description of materials used to produce product		67702	OWN	
880.1200	Description of production process		67702	OWN	
880.1400	Discussion of formation of impurities		67702	OWN	
830.1700	Preliminary analysis		67702	OWN	
830.1750	Certified limits		67702	OWN	
830.1800	Enforcement analytical method		67702	OWN	
830.6302	Color				N.A.
830.6303	Physical state		67702	OWN	
830.6304	Odor				N.A.
830.6315	Flammabilty				N.A.
830.6316	Explodabilty				N.A.
830.6317	Storage stability		67702	OWN	Waiver Request
830.6319	Miscibility				N.A.
830.6320	Corrosion characteristics		67702	OWN	Waiver Request
830.6321	Dielectric breakdown voltage				N.A.
830.7000	pH		67702	OWN	

Signature W G Talarek	**Name and Title** Walter G. Talarek Authorized Agent	**Date** 12/16/09

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DATA MATRIX (Product-Specific)

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Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	Product: Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity				N.A.
830.7300	Density, bulk density or specific gravity		67702	OWN	
870.1100	Acute oral toxicity		67702	OWN	Waiver Request
870.1200	Acute dermal toxicity		67702	OWN	Waiver Request
870.1300	Acute inhalation toxicity		67702	OWN	Waiver Request
870.2400	Primary eye irritation		67702	OWN	Waiver Request
870.2500	Primary dermal irritation		67702	OWN	Waiver Request
870.2600	Skin sensitization		67702	OWN	Waiver Request

Signature	Name and Title Walter G. Talarek Authorized Agent	Date 12/16/09

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Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	**Product:** Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
			67702	OWN	
					N.A.
			67702	OWN	
					N.A.
					N.A.
					N.A.
			67702	OWN	Waiver Request
					N.A.
			67702	OWN	Waiver Request
					N.A.
			67702	OWN	

Signature WGTalarek

Name and Title Walter G. Talarek
Authorized Agent

Date 12/16/09

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DATA MATRIX (Product-Specific)

Date: December 16, 2009	**EPA Reg. No./File Symbol:** 67702-	**Page** 2 of 2
Applicant's/Registrant's Name & Address W. Neudorff GmbH KG An der Muhle 3 31860 Emmerthal, Germany	**Product:** Slugkil MP	

Ingredients – Sodium ferric EDTA

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					N.A.
			67702	OWN	
			67702	OWN	Waiver Request
			67702	OWN	Waiver Request
			67702	OWN	Waiver Request
			67702	OWN	Waiver Request
			67702	OWN	Waiver Request
			67702	OWN	Waiver Request

Signature	**Name and Title** Walter G. Talarek Authorized Agent	**Date** 12/16/09

Neudorff North America · P.O. Box 178 · Brentwood Bay, B.C. · Canada V8M 1R3

NEUDORFF®
natural gardening

20 November 2009

Linda Hollis, PM 91
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (APPL))
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460-0001

Re: **Authorization of Registration Agent for Neudorff's Slugkil 2, Slugkil 5 and Slugkil MP**

Dear Mrs. Hollis,

I hereby authorize Walter G. Talarek, PC as W. Neudorff GmbH KG's ("Neudorff's") agent and representative for the purpose of registering its Slugkil 2, Slugkil 5 and Slugkil MP product containing Ferric Sodium EDTA as the active ingredient. This authority includes, without limitation, the authority to sign all documents necessary to effect this purpose and to access all confidential information and files that have been or will be submitted in support of Neudorff's applications for registration.

Sincerely yours,

C D Wilson

Cameron Wilson
VP/Operations Manager
Neudorff North America

Neudorff North America · P.O. Box 178 · Brentwood Bay, B.C. · Canada V8M 1R3
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W. Neudorff GmbH KG · An der Muehle 3 · 31860 Emmerthal · Germany
www.neudorff.de

Pages-210-218 *Confidential Statement of Formula may be entitled to confidential treatment*